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NO. 1

OTC Drugs for Use in the Eye

— J. Richard Wuest
— Thomas A. Gossel

Hypertension, Diuretics and the Elderly

— Peter P. Lamy

"Freedom of Choice" Patient Information Leaflet.

THE MARYLAND PHARMACIST

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President's Message

A SPECIAL INVITATION . . .

A nucleus of recent graduates,* euphemistically called "young pharmacists" met together in early October for the first-ever get-together of the Young Pharmacists' Caucus of the Maryland Pharmaceutical Association. We enjoyed renewing friendships, catching up on pharmacy gossip, talking about what we'd like to see MPhA do for us and how we can serve pharmacy within MPhA.

The group expressed special concern with regard to our need to improve communications about association activities. "We don't know what's happening and need to feel more in the mainstream." "Give us sufficient notice so we can adjust our work schedules." Brad Thomas, along with Dudley Demarest, have taken the initiative, and will start a newsletter for the Y.P.C. so we can keep you up to date, in addition to our monthly association newsletter. Send me your name to get on our mailing list.

More than half the group in attendance volunteered to serve on association committees. Most popular committee choices are: Employer/Employee Relations Committee, Legislative Committee, Professional Affairs and Industry Relations.

We also made a pact—as a group—to attend the Mid-Year Meeting of the Maryland Pharmaceutical Association on Feb. 2, in Annapolis. Many of us agreed to bring along at least one new person along (although many in this group are expecting parents, or new parents, offspring will not count!!).

Will you join us as well and add to our core of "Young Pharmacists." Remember that "young" is merely a state of mind. Be there, for good friendship, good food, good C.E. and let's do some good work for pharmacy.

* The nucleus
Rick Battersby '80
Terry Davis
Evelyn Farinas
Kathy Gauthier
Glen Miles
Betty Moses
Kathy Parker
Matt Shimoda
Brad Thomas
Nancy Baros
Bill Forrest
Mark Gladson
Anna Charuk (special guest)
Angelique Kariotis
Mark Zellhofer
Rick Thompson
Beverly Yachmetz
Dudley Demarest
Phil Fink
Jim Apostolou
Scott Fisher
Janet Holsopple
Karen Lewis
Joe Demina
Dale Klemm
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SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. II, NO. 12

Advising Consumers On Eye Preparations Part II: OTC Drugs For Use In The Eye

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and

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Goals

The goals of this lesson are to:

1. describe OTC eye preparations currently available and those unsuitable for OTC use;
2. explain how to advise patients on the proper instillation of ophthalmic products.

in the service of pharmacy

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Objectives

At the completion of this lesson, the successful participant will be able to:

1. identify ophthalmic preparations approved for OTC sale;
2. explain the proper technique for instilling OTC ophthalmic products;
3. know when to refer the patient to a physician.

This lesson reviews OTC eye preparations currently available and those likely to be banned from future OTC sale. Part I of this series reviewed the anatomy and physiology of the eye, and the ocular disorders which are self-treatable.

The FDA Advisory Panel on OTC Ophthalmic Drugs has determined that there are six types of ocular products appropriate for self medication: astringents, demulcents, emollients, hypertonic agents, vasoconstrictors and eye washes that contain no active ingredients. Drugs considered safe and effective for these uses are listed in Table 1.

Astringents

Astringents are substances that precipitate protein in cells on the surface of epithelial tissue. When used on skin or non-ocular mucous membranes, they provide a protective and sometimes styptic activity. This action could damage the corneal epithelium. However, one astringent, **zinc sulfate,** in a 0.25% solution, is mild and reportedly helps remove mucus from the corneal epithelial tissues. This provides relief from discomfort of minor eye irritations without damaging the cornea itself.

Demulcents

Demulcents are high molecular weight, water-soluble substances that are applied to the eye to protect and lubricate mucous membrane surfaces and relieve dryness and irritation. To some extent they mimic the "natural" demulcent, mucus. They coat the surface of the ocular tissues and protect it from external stimulation. Demulcents are also used to treat dry eyes, and to increase the viscosity of solutions of ocular drug products. Several cellulose derivatives and high molecular weight alcohols have been approved for this use. A complete list appears in Table 1.

TABLE 1
Safe and Effective OTC Ophthalmic Products*

ASTRINGENTS
- Zinc Sulfate

DEMULCENTS
- Carboxymethylcellulose
- Dextran 70
- Gelatin
- Glycerin
- Hydroxyethylcellulose
- Hydroxypropyl methylcellulose
- Methylcellulose
- Polyethylene glycol (300-6000)
- Polysorbate 80
- Polyvinyl alcohol
- Povidone
- Propylene glycol

EMOLLIENTS
- Anhydrous lanolin
- Lanolin
- Light mineral oil
- Mineral oil
- Paraffin
- Petrolatum
- White ointment
- White petrolatum
- White wax
- Yellow wax

EYE WASHES
- With no active ingredients

HYPERTONIC AGENTS
- Sodium chloride (2-5%)

VASOCONSTRICTORS
- Ephedrine HCl
- Naphazoline HCl
- Oxymetazoline**
- Phenylephrine HCl
- Tetrahydrozoline HCl

*As proposed by FDA 6/83
**At the time of original publication of this article, Afrin eye drops were approved by FDA.

Ophthalmic demulcents are used as tear substitutes and as contact lens lubricants. They are also used to relieve the symptoms of irritation caused by airborne irritants and allergens, and exposure to wind and sun.

Emollients

Emollients are oily/fatty substances that are applied to eyelids to protect or soften tissue, and to prevent drying and cracking of tissue. On the skin, emollients are widely used to soften, protect, and prevent drying by forming an occlusive, oily film that holds moisture on and in the stratum corneum.

Emollients can lubricate the conjunctiva and cornea in tear deficiency, prevent irritation from airborne irritants, and prevent excessive loss of moisture from the cornea. They also form the basis for ophthalmic ointment vehicles. Those that have been approved for OTC use (and for prescription products as well) are derivatives of lanolin, petrolatum, wax or other hydrocarbons.

Often the ointment base is a combination of various emollients. For example, lanolin, wax, and paraffin are not appropriate for direct application in their natural forms. But they are excellent for incorporating drugs into, and increasing the consistency of other ointment bases.

Ocular emollients temporarily relieve minor irritations of the eye, dryness, and exposure to sun and wind. They are listed in Table 1.

Eye Washes

Eye washes are defined as sterile, aqueous solutions intended for bathing or mechanically flushing the eye. They do not contain pharmacologically active ingredients. Instead, they are composed of combinations of the various substances listed in Table 2. Eye washes are indicated for diluting or removing irritants such as foreign bodies, pollen, and noxious chemicals (e.g., airborne pollutants, chlorinated water) from the eye. This overcomes the eye's natural reflex of uncontrolled blinking and alleviates the discomfort, burning, itching, smarting, and stinging sensations.

Eye washes should not be used if the eye is damaged. When the eye is damaged, its defense mechanisms are compromised and physician intervention is necessary.

TABLE 2
Substances Suitable for Ophthalmic Formulations

BUFFERING AGENTS
- Acetic acid
- Boric acid
- Hydrochloric acid
- Phosphoric acid
- Potassium bicarbonate
- Potassium carbonate
- Potassium citrate
- Potassium phosphate
- Potassium tetraborate
- Sodium acetate
- Sodium bicarbonate
- Sodium biphosphate
- Sodium borate
- Sodium carbonate
- Sodium citrate
- Sodium hydroxide
- Sodium phosphate

PRESERVATIVES
- Benzalkonium chloride
- Benzethonium chloride
- Chlorobutanol
- Parabens
- Phenylmercuric acetate
- Phenylmercuric nitrate
- Thimerosal

STABILIZING AGENTS
- Edetates (EDTA)
- Sodium bisulfite
- Sodium metabisulfite
- Sodium thiosulfate
- Thiourea

TONICITY AGENTS
- Calcium chloride
- Dextrose
- Magnesium chloride
- Potassium chloride
- Sodium chloride

VISCOSITY AGENTS
- Cellulose derivatives
- Dextran
- Gelatin
- Glycerin
- Polyethylene glycols
- Polysorbate
- Polyvinyl alcohol
- Povidone
- Propylene glycol

Hypertonic Agents

Hypertonic agents are substances that exert a greater osmotic pressure than the surrounding fluids and tissues from which they draw water. When applied to the eye, these agents create an osmotic gradient that attracts water from the midportions of the cornea. Although the epithelial (outermost) and endothelial (innermost) layers of the cornea are basically lipid, the midportion contains water, as does the sclera. Excessive buildup of water leading to corneal edema can occur. When it does, visual acuity is hampered.

All living tissues, including the corneal epithelial cells, are semipermeable, i.e., water but not particles may diffuse through. Osmotic pressure is one of the laws of nature. It means that water will move through a semi-permeable membrane from an area with a lower concentration of dissolved molecules or ions to an area with a greater concentration of particles. Osmotic pressure is an attempt to equalize the concentration of particles on both sides of the membrane.

In corneal edema, a hypertonic preparation would draw excess fluid from the cornea and improve eyesight. Corneal edema cannot be self-diagnosed. However, once it has been diagnosed by a physician, self-medication is possible.

It is not always possible or desirable to correct the underlying cause of corneal edema. Oftentimes the underlying cause cannot be determined. Hypertonic preparations do not cure the condition, but they relieve the symptoms. For this reason and because they are innocuous, approved hypertonic agents (sodium chloride 2-5%) are available OTC.

Personal preference dictates whether the ointment or solution form is better. Several studies have found that 5% sodium chloride ointment in a petrolatum and wool fat base is more effective for reducing corneal edema than lower strengths or the 5% solution. With contact lenses, especially the hydrophilic bandage type, the solution is preferred. There is less chance of it impeding visual acuity since the ointment may be deposited on the lens.

Ocular Vasoconstrictors

Ocular vasoconstrictors are agents that cause temporary constriction of the blood vessels in the conjunctiva when applied to ocular mucous membranes. Those that have been approved for OTC sale are ephedrine, naphazoline, phenylephrine and tetrahydrozoline in relatively low strengths. Oxymetazoline (Afrin^{R} eye drops) was approved by FDA but not marketed at the time of original publication of this lesson.

These agents stimulate the adrenergic receptors in blood vessels in irritated conjunctiva, thereby constricting them. This action can relieve ocular irritation. Higher doses are used on a prescription-only basis to produce mydriasis (dilation of the pupil), and, in open-angle glaucoma, to lower intraocular pressure. Conversely, in narrow-angle glaucoma, ocular vasoconstrictors can raise intraocular pressure and are contraindicated.

When the cornea or conjunctiva is irritated, tear secretion increases in an attempt to dilute or remove the irritating substance. At the same time, the blood vessels underlying the sclera dilate as part of the inflammatory response and white blood cells migrate to the area. All this results in hyperemia (excessive blood flow) and edema, commonly called "redness" of the eye.

Minor reactions of the eye to irritating substances can be alleviated with the use of eye washes that contain no active ingredients. If, however, itching and redness persist, low-strength vasoconstrictors can be used to constrict the overly dilated blood vessels and relieve the condition. In some individuals, therapy including a vasoconstrictor plus the astringent zinc sulfate can enhance anti-irritant activity. This particular combination is also included in the safe and effective OTC ophthalmic drug category.

If the problem persists after a few days of self-medication, the individual should contact a physician due to the possibility of ocular damage.

Ophthalmic Products Unsuitable for OTC Use

The two major groups of ophthalmic products that the FDA considers unsuitable for OTC use are the anti-infectives and local anesthetics. **Anti-infectives** are included in spite of the fact that boric acid, mild silver protein, thimerosal and yellow mercuric oxide have been available and widely used for self-medication for a long time.

Boric acid has known toxicity problems. An adult toxic dose of 5 gm boric acid has been reported. Therefore, a 4-ounce bottle of a saturated boric acid solution is a potentially toxic (even lethal) dose for an adult, and much less is toxic to a child.

The effectiveness of boric acid as an antimicrobial agent is questionable since few studies have been completed to prove its effectiveness. This is because any infection that is self-treatable is probably self-limiting. The use of boric acid in the eye is based solely on empiricism.

Mild silver protein is included in the same category. Prior to the advent of antibiotics, mild silver protein was widely used in the treatment of eye infections. But, there has never been any documentation to establish its effectiveness.

The mercury-containing substances such as **thimerosal** and **yellow mercuric oxide** represent a dichotomy. There is no doubt that mercurials are effective preservatives. When they are present in a sterilized solution, they can inhibit growth of invading microorganisms introduced into the container.

However, evidence that they prevent the growth of microorganisms when applied to infected tissues does not exist. Mercurials owe their antimicrobial action to the mercuric ions. These ions, on entry into susceptible microorganisms, denature protein and kill (or prevent the growth and reproduction of) the microorganisms. While this is fine when the mercurials are present in a solution as a preservative, they are overwhelmed by the protein and salts in human tissue when applied to active infections. They are, therefore, ineffective antimicrobials.

The FDA stated that the benefits associated with OTC availability of anti-infectives is exceeded by the risks of inappropriate self-diagnosis, inappropriate self-medication, and toxicity. Contemporary feeling is that self-treatable infections are actually self-limiting and, therefore, need no treatment. Those that require treatment need physician intervention and supervision.

It has been proposed that all currently available OTC anti-infectives be removed from the market. Unless documentation of their safety and effectiveness can be established, they undoubtedly will be removed.

Local anesthetics are the second group of ophthalmic agents that are considered to be inappropriate for OTC use. There are several risks associated with their unsupervised use. They may mask symptoms of imbedded foreign bodies, corneal abrasions, or an eye disease that requires medical attention. Local anesthetics may delay or prevent treatment of eye diseases that require diagnosis by a physician. Therefore, they have been placed in the "banned from future sale" category, i.e., Category II.

Pharmaceutical Necessities Used In Eye Drugs

Eye drops are diluted by tears and quickly removed by tear flow. Substances in tear fluid can bind with or degrade drugs causing them to lose their activity. The conjunctival area is a relatively large surface in relation to the volume of a drop of solution. For these and other reasons, drug dynamics can be greatly altered by such factors as tonicity, pH, protein binding, irritating capacity, metabolism, stability and compatibility of the drug. Therefore, many factors must be considered in ocular drug therapy because they all affect pharmacologic activity.

The eye is an extremely sensitive organ which rapidly reacts to most changes in the environment. Therefore, special attention should be given to their active ingredients, additives, buffering, clarity, hydrogen ion concentration, packaging, preservatives, stability, sterility, tonicity, and viscosity.

Generally, eye drops are buffered, isotonic and self-sterilizing, and at times, highly viscous. Buffering assures the stability of the active ingredients since most are weak acids or weak bases. However, the buffering system must also allow the tear fluid to readjust to its normal pH of 7.4 after application of the drop. Antioxidants are needed for some drugs to assure their stability. Isotonicity is required to minimize discomfort when the drug is applied, but there is considerable leeway here because the eye can tolerate a tonicity range from 0.5 to 1.8% sodium chloride.

The most important factor in relation to eye drops is sterility. By law, all eye drops must be sterile (regardless of how or by whom they are manufactured). If they are dispensed in a multiple use package, they must contain a preservative. This is to prevent the growth of microorganisms that might be introduced during use. Table 2 lists the pharmaceutical necessities that are considered to be suitable for ophthalmic products.

Consumer Advice On OTC Ophthalmic Products

Demulcents. There are no overt side effects associated with the use of demulcents in the eye. Cellulose derivatives that seep out of the eye onto the lid and lashes can dry out and form crusts on the eyelids. Some individuals may be annoyed by this, but the crusts can be easily removed with warm water.

Some demulcents may cause a transient stinging or temporary blurred vision. Neither of these effects is serious unless it persists or annoys the person. If so, some other agent should be used.

Emollients. Emollients cause temporary blurred vision because they initially form an oily film over the cornea. This is not harmful since the film will only last from several blinks to a few minutes. While this is innocuous, it should be explained to small children before application of ophthalmic ointments so they know what to expect.

Vasoconstrictors. There is a conservative view that ophthalmic medications, most specifically the vasoconstrictors, may cause toxicity due to absorption through the conjunctival capillaries into the circulation. Absorption can occur from the nasal mucosa, oral pharynx, or gastrointestinal tract after the drug passes through the nasolacrimal duct which drains the conjunctival sac. Toxicities, usually relating to their cardiovascular effects (e.g., hypertension, cardiac irregularities) or CNS stimulation, have been reported for high-strength ophthalmic vasoconstrictors.

While systemic absorption of OTC ophthalmic drugs is theoretically possible and probably occurs to a limited extent, toxicity is of little concern to the consumer. Toxicity reports that describe serious cardiovascular or central nervous system involvement relate to drug concentrations that are available only by prescription. The short-term use of OTC ophthalmic vasoconstrictors is unlikely to cause systemic toxicity.

Eye Washes. Eye washes using a nozzle directly from the container should be applied in a steady stream. A towel or utensil such as an emesis basin should be used to catch the run-off.

For washes used with an eye cup, the cup should be rinsed with tap water before and after each use to minimize the chance of contamination. The recommended method of using an eye cup is to fill it halfway with eye wash, press the cup tightly to the area around the affected eye, look downward, and tilt the head backward. The person should open the eyelid as much as possible and rotate the eyeball. This is to insure complete irrigation of the eye.

The patient should consult a physician if severe eye pain, headache, visual change, floating spots, increased or persistent redness, or photophobia (excessive squinting or fear of bright light) is experienced.

Consumers should also be advised not to use any discolored or cloudy eye preparations and to avoid contamination of the tip of the container during use.

Eye Drops. To properly instill eye drops, the individual should wash his hands thoroughly and gently pull the lower eyelid down with one hand. The container should be held above the eye and gently squeezed to allow a drop to fall inside the lower lid while looking up. Patients who flinch when instilling eye drops should lay the neck of the dropper unit (that contains the spiral bevel where the top screws on) across the bridge of the nose so that the tip of the dropper is just above the eye and the drop cannot be seen as it falls in.

After the drop has been instilled, the individual should release the lower lid but try to keep the eye open and not blink for at least 30 seconds. This will allow a greater distribution of the drug and minimize the amount that would be squeezed out during blinking. Consumer advice on the proper use of eye preparations is listed in Table 3.

Eye Ointments. The patient should thoroughly wash his hands before applying an ophthalmic ointment. The patient should gently pull the lower eyelid down with one hand, look up, and squeeze a small amount (¼ to ½ of the length of the lower lid) of ointment along the lower lid. After application, the eyelid should be gently closed, and the eyeball rolled in all directions without squeezing the eye too tightly shut. The end of the tube should not touch any surface, and the cap should be replaced as soon as possible. Individuals having difficulty self-applying an eye ointment can instill the ointment while sitting in front of a mirror with their elbows resting on the edge of a sink, or table.

TABLE 3
Consumer Advice on the Proper Use of Eye Preparations

EYE DROPS
- Wash hands thoroughly.
- Gently pull down lower lid.
- Hold the container just above the nose-end of the eye, or lay it across the bridge of the nose.
- Squeeze the container slightly.
- After application, release the lower lid and try to keep the eye open for at least 30 seconds.
- Try not to blink too hard or this will squeeze the medication out of the eye.
- Do not touch the dropper tip to any surface.
- Close and tighten the container as soon as possible.
- Do not open back-up bottles of eye drops until the currently used one is empty.
- Watch the expiration date on the container and do not use outdated, discolored or cloudy drops.
- If you have trouble determining if the drops have actually been applied to the eye, keep your eye drops in the refrigerator. The cold receptors in the eye will signal that the drop has been instilled.

EYE OINTMENTS
- Wash hands thoroughly.
- Gently pull down the lower lid.
- Hold the tip of the tube slightly above the inside portion of the cuticle sac of the eye.
- Squeeze a small amount of ointment (¼ - ½ inch) inside the lower lid.
- After application, reclose the lower lid gently, close the eyelid and roll the eyeball around in all directions.
- Do not squeeze too tightly.
- Remember that momentary blurred vision may occur.
- Do not touch the top of the tube to any surface and re-cap it as soon as possible.
- Do not open back-up tubes until the current, in-use one is empty.
- Watch the expiration date on the container and do not use outdated ointments or those with precipitate present.
- If you have trouble administering the ointment, sit in front of a mirror with your elbows stabilized on a sink or table.

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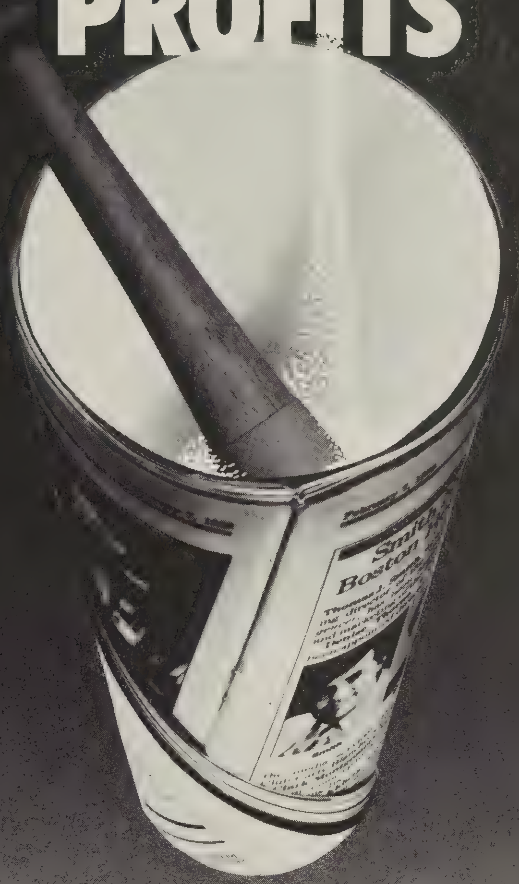

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Hypertension, Diuretics, and the Elderly

By Peter P. Lamy, Ph.D.

The incidence and prevalence of coronary artery disease and hypertension increases with age. Among persons 18 to 24, mean systolic blood pressure is 122 mm.Hg.; for those 75 to 79, it is 154 mm.Hg. Past the age of 65, some 30 to 40 percent of the population have blood pressure readings exceeding the World Health Organization standard of 160/95 mm.Hg.

Drug use by the elderly reflects these statistics. The nine drugs most used in 1981 by those 85 and older include three diuretics (hydrochlorothiazide, furosemide, and triamterene), two cardiovascular agents (digoxin and isosorbide dinitrate), and potassium products. Aspirin ranks high, often given in a once-a-day dosage.

It is interesting to note that vitamin B-12 ranks seventh on that list and is most often given without any indication, obviously as a placebo, and Papaverine, which had not yet been found to be effective by the Food and Drug Administration, ranks eighth.

Treatment

There is no question but that moderate to severe hypertension should be treated. The clinician, however, should take several factors into consideration. First, it is important to realize that the elderly are more sensitive to volume depletion and sympathetic inhibition due to impaired cardiovascular reflexes. Also, the elderly are more sensitive to hypotension. Thus, in treating the elderly, one should start with smaller than usual doses. Increases should also be small and at longer than usual intervals.

Certainly the quality of life of a patient placed on antihypertensive therapy may be altered substantially. The medication may be responsible for sedation, impairmant of intellect, sleep disturbance, and sexual dysfunction. An increased frequency of CNS effects due to antihypertensives is also reported, and elderly women are particularly at risk. All of these factors may lead to non-compliance, and, indeed, a British study shows that more than one-third of the elderly fail to comply with the prescribed antihypertensive regimen. Other studies have found that as many as 25 to 50 percent of older persons default completely.

Mild hypertension

Evidence of the beneficial effect of treatment of mild hypertension is still unconvincing to many health professionals. Studies show that protection from strokes can be achieved with antihypertensives, but protection from heart attacks has not been conclusively demonstrated. So there is still no uniform policy regarding treatment of mild hypertension in the elderly. Sometimes, if no other risk factors are present, it may be better to delay the start of treatment. Any change in the patient's condition should then determine when treatment is appropriate.

In short, therapy should be individualized. Treatment is indicated, however, if diastolic pressure is consistently over 100 mm.Hg. and systolic is over 160 mm.Hg. It is generally agreed that treatment should not be too vigorous.

Therapy goals

The old goals of antihypertensive treatment are no longer sufficient. It is not enough, for instance, simply to determine whether a specific drug lowers an elevated blood pressure. The treatment goals should include maintaining a patient's physical and mental efficiency and, if possible, improving that efficiency as compared with his untreated state. Furthermore, the antihypertensive drug should protect the patient against stroke, left ventricular hypertrophy, and congestive heart failure as well as against more severe hypertension.

Another goal should be to control the patient with monotherapy. In general, 40 to 60 percent of patients respond successfully to the use of one drug. The use of multiple agents will often increase the patient's risk to adverse drug reactions.

Finally, keep in mind that reports are beginning to appear in the literature indicating that antihypertensive treatment may well not necessarily be lifelong treatment. In one recent study, treatment was withdrawn from 105 elderly. Forty-one percent of those patients were still normotensive after 11 months.

New approaches

It has been suggested abroad that beta-blockers or converting enzyme inhibitors be considered the first drug for young, high-renin patients. For patients over 60 and low-renin patients, the suggestion has been made that calcium channel blockers or perhaps even converting enzyme inhibitors be first drug. There are indications that the converting enzyme inhibitors are effective in normal and even low-plasma-renin patients.

THE AUTHOR is professor and director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, and chairman, department of pharmacy practice, School of Pharmacy, University of Maryland, Baltimore.

While calcium channel blockers have not yet been approved for treatment of hypertension in this country, one might consider that they are cleared via the liver, and one must expect reduced clearance in the elderly. Cimetidine, often given to elderly, would reduce hepatic blood flow and further reduce clearance. Also, calcium channel blockers may cause hypotension in the elderly. Further, if a diuretic were added to this regimen, elderly patients might well be faced with severe volume depletion.

The place of beta-blockers in antihypertensive regimens for the elderly is still questionable. They are viewed as first-line drugs for patients at risk to infarction, arrhythmias, or acute ischemic disease. But, as the accompanying table shows, their use declines with advanced age, possibly because of side effects. They increase blood lipids and peripheral resistance and may cause fatigue and the cold-limb syndrome. Mainly, however, use declines because beta-receptors change with age.

The "protective" effect of beta-blockers is also somewhat questionable. While there is no doubt that they can protect a patient against recurrent myocardial infarction, documentation is still lacking as to whether they can protect a patient against an initial MI. Some clinicians have noted that atenolol, nadolol, and labatolol do not appear to affect serum creatinine, urea, and the glomerular filtration rate and could, therefore, be alternatives to diuretics in the elderly.

Labatolol is the first antihypertensive to combine beta-blocker and vasodilator properties. It relaxes blood vessels without significantly changing heart rate and may, therefore, be attractive for use in geriatric patients. Because of its vasodilator properties, though, it should not be used in elderly persons who have a history of dizziness when rising to stand.

For elderly hypertensive diabetic patients, either the alpha-blocker prazosin or the central active agent clonidine is recommended. Neither interferes with carbohydrate or lipid metabolism, and neither drug exacerbates hypoglycemia. If a beta-blocker is selected for initial therapy, it should be a cardioselective one since it would cause less interference with recovery from hypoglycemia.

Diuretics

Sustained hypertension may be due to increased blood-flow resistance, increased vasoconstrictor tone, or increased sensitivity of vascular smooth muscle. Diuretics act by promoting salt and water loss and are thus very useful as first-line agents in almost all types of hypertension. They also potentiate the effect of many other antihypertensives.

Before starting a patient on a diuretic, the patient's intravascular volume should be assessed. If increased, as in congestive heart failure, rapid diuresis is less risky. If normal or depleted, as in cirrhosis or the nephrotic syndrome, rapid diuresis is risky. In general, rapid diuresis is a risk in the elderly unless there is a hypertensive crisis. Diuretics that act at the glomerulus, proximal tubule, or thick ascending limb of the loop of Henle cause both sodium and potassium loss. Those acting at the distal tubule and the collecting duct cause potassium retention. The latter are called "loop" or "high ceiling" diuretics.

In most elderly patients, a diuretic is the only agent required. The lowest possible dose should be selected, and the patient should be observed for four to six weeks. If no positive response can be obtained, the dose of the diuretic should not be increased. Another agent should be added to the regimen.

There is increasing concern about possible or potential side effects of diuretics, particularly in the elderly. Fatigue and weakness may occur because of decreased perfusion of muscle, hypokalemia, and hyponatremia. Studies warn against hypokalemia, which can lead to ventricular ectopic activity and sudden death, hyperglycemia, hyperuricemia, and hypercholesterolemia. The elderly may experience confusion, dehydration, and sexual dysfunction. Orthostatic hypotension can be a major problem, as can volume depletion, especially in the presence of fever, diarrhea, and loss of thirst sensation. A British study, published in 1980, shows that diuretics caused the largest number of side effects in the elderly.

Interactions of diuretics and other drugs may occur with many medications frequently used by the elderly. Since 80 percent of all non-steroidal antiarthritic drugs are prescribed for the elderly, it is important to note

Cardiovascular drugs
Number of prescriptions per 1,000 patients per year

	Age				
Category	0–44	45–54	55–64	65–74	75+
Beta-blockers	53	415	676	800	638
Thiazide diuretics	36	295	496	679	693
Digitalis	6	56	191	521	1,071
K-sparing diuretics	31	281	460	628	774
Other oral diuretics	15	106	249	521	880
Other antihypertensives	18	194	371	495	501
Nitrites/nitrates	7	140	348	589	739

Source: FDA Drug Analysis Branch. Based on IMS National Prescription Audit and National Disease and Therapeutic Index, 1984.

Disorders precipitated or exacerbated by antihypertensives

Depression	Clonidine, methyldopa propranolol, reserpine
Diabetes mellitus	Furosemide, thiazides
Gout	Loop and thiazide diuretics
Headache	Hydralazine, prazosin
Hypercalcemia	Chlorthalidone, thiazides
Organic brain syndrome	Clonidine, methyldopa, propranolol, reserpine
Parkinson's disease	Reserpine
Peptic ulcer disease	Reserpine
Peripheral vascular disease	Beta-blockers
Sick sinus syndrome	Beta-blockers, verapamil
Urolithiasis	Acetazolamide

that the non-steroidals can interfere with the action of beta-blockers, converting enzyme inhibitors, and diuretics to a clinically significant degree. Systolic blood pressure may rise by about 15 mm.Hg. and diastolic pressure by seven to 10 mm.Hg.

The interaction between diuretics and non-steroidal drugs is probably due to the elimination of the independent natriuretic action of the renal prostaglandins. An association has been suggested, on the other hand, between use of non-steroidals and acute renal failure. At greatest risk are patients with volume depletion, the elderly, and those receiving diuretics.

Two serious issues have been raised in regard to the use of diuretics. First, it has been suggested that probably all antihypertensives affect lipid metabolism. The levels of plasma triglycerides and very low-density lipoproteins may be raised, sometimes substantially. It has also been noted that this effect may increase coronary risk and offset the beneficial effect of lowering blood pressure.

The second issue was raised after studies showed that diuretic treatment of hypertensive men with certain ECG abnormalities increased the risk of coronary heart disease mortality significantly. However, it is also argued that men should therefore be treated for hypertension before these ECG abnormalities occur.

The increased mortality has been related to hypokalemia. Thus, there is renewed interest in the need for the use of potassium supplements in patients treated with diuretics. One should not forget, however, that many elderly patients purchase potassium supplements in health food stores, many drink orange juice and eat bananas, and many have switched or were asked to switch to salt supplements, which can contain considerable amounts of potassium. Non-fat milk that the elderly are likely to drink also contains more potassium than either whole or skim milk. Thus, undirected potassium intake may be high among the elderly population, and the use of a potassium-sparing diuretic or a potassium supplement may then lead to hyperkalemia. At heightened risk are elderly diabetic patients. Incidentally, beta-blockers may enhance the hyperkalemic risk.

Accompanying tables show the prevalence of serum potassium levels of less than 3.5 mEq/l that are likely to occur when using diuretics and suggest some action when hypokalemia occurs. Serum potassium levels above 3.5 mEq/l do not usually call for use of potassium supplements. However, a drop of 0.5 mEq/l warrants careful follow-up. When a potassium supplement is needed, potassium citrate may be better than potassium chloride for patients receiving thiazides in whom stones form.

An additional note of caution is indicated. The use of anticholinergics for the elderly is relatively high. Gastric emptying time is slowed considerably with advancing age. The use of gastrokinetic drugs is increasing, and some of them decrease gastric emptying further. If an elderly patient receives a potassium supplement via the wax-matrix dosage form, which increases the risk of gastric erosion, then further slowed gastric emptying would increase that risk.

The thiazides: In hypertension due to renal abnormalities, fluid retention often occurs. Thiazides would then be a logical choice to use as a first-line drug. Since thiazides reduce blood pressure by normalizing peripheral resistance, they have been used consistently as the first drug in primary hypertension. These diuretics produce an average loss of two liters of extracellular fluid (300 milliliters plasma volume) in the first 48 hours, and that loss is maintained as long as the drug is given.

Clinically, all thiazides are virtually equivalent, except for the dose in milligrams. A dose-response plateau is reached and any increase in dose has little effect, except to increase the severity of side effects. The thiazides lose their diuretic effectiveness if the glomerular filtration rate decreases. They are not effective if GFR is less than 25 milliliters per minute.

The most frequent side effects are predictable. One recent development concerns the bioavailability of the active ingredient from chlorothiazide tablets. It has now been shown that, regardless of tablet strength, only 50 milligrams is available. Thus, increased diuresis is not obtained by using one larger-strength tablet but by using two less-concentrated ones.

Diuretics may induce magnesium depletion, particularly in the elderly with low magnesium intake. Digitalis, quite often prescribed for the elderly, induces arrhythmias more often in patients with hypomagnesemia. Thiazide-induced hyperuricemia is treated with probenecid, which should also be used in patients with a pretreatment history of gout. If the patient is a hyperproducer of uric acid, allopurinal is generally recommended. Thiazides (and chlorthalidone) also can increase urinary zinc excretion, more so in patients with renal insufficiency. Finally, since these diuretics are sulfonamides, it is not surprising to note that the elderly

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Potential side effects of diuretics

Increase catecholamines, angiotensin, free fatty acids, ventricular ectopic activity, hematocrit, platelet aggregation.

Decrease potassium, glucose tolerance, high-density lipoprotein cholesterol.

Source: Buehler, F. R., 9th International Congress on Pharmacology, London, 1984

Diuretics and hypokalemia
Prevalence of serum K less than 3.5 mEq/L:

Hydrochlorothiazide, 50 mg.	11.0%
Chlorthalidone, 25 mg.	8.1%
Triamterene, 100 mg., HCTZ 50 mg.	5.3%
Furosemide, 40 mg.	3.5%
Hydrochlorothiazide, 25 mg.	2.2%

Source: Licht, J. H. et al., Archives of Internal Medicine, 143:1694, 1983 not infrequently present with rashes on initial treatment with thiazides.

The loop diuretics: This class of diuretics is often used inappropriately in mild to moderate hypertension. These diuretics are indicated when a patient does not respond to thiazides, when creatinine clearance is less than 40 to 50 milliliters per minute, or when emergency diuresis is needed. Patients with decreased renal function have less intense but a more prolonged response to loop diuretics. They would need higher doses, but that, of course, increases the potential of toxicity. The risk of ototoxicity is enhanced by concurrent administration of aminoglycosides.

Care should be exercised in using this class of drugs for the elderly, as strong diuresis can lead to volume depletion and cardiovascular collapse. It is generally agreed that furosemide and bumetanide are less ototoxic than is ethacrynic acid. Bumetanide is 70 times more potent than furosemide. When a patient is switched from intravenous furosemide to an oral dose, the change requires a doubling of the dose. This is not true for bumetanide.

When furosemide is prescribed for elderly patients with normal cardiac and renal function, the starting dose should be lower than the normal adult dose. In elderly patients with congestive heart failure, the normal adult dose constitutes the initial dose. The elimination half-life of furosemide is prolonged in the elderly, and clearance is reduced, which leads to higher blood levels. Nevertheless, there is a decreased diuretic effect, since less drug reaches the active site. Finally, it has been reported that slow-release furosemide offers advantages in CHF maintenance therapy in the elderly.

The potassium-sparing diuretics: Amiloride, spironolactone, and triamterene constitute the available potassium-sparing diuretics. They are often used in combination with thiazides to prevent potassium loss, but the rationale of this combination is debatable. Triamterene should not be used for patients on non-steroidal therapy. The potassium-sparing diuretics are indicated in secondary hyperaldosteronism, in patients refractory to large doses of loop diuretics, or in cirrhotic patients with intractable ascites.

When prescribing potassium-sparing diuretics for the elderly, one should keep in mind that the risk of hyperkalemia is greater than the risk of potassium depletion.

Diuretics and hypokalemia

If patients on hydrochlorothiazide, 50 mg., develop hypokalemia, use 25 mg.
Furosemide, 40 mg., is the most cost-effective alternative.
Reserve chlorthalidone when HCTZ or furosemide is not tolerated.
For K conservation, spironolactone or triamterene together with HCTZ offer no benefit over furosemide.

Source: Licht, J. H., et al., Archives of Internal Medicine, 143:1694, 1983

Pharmacy Support Needed for Poison Prevention Week March 16–22, 1986

In Maryland, Poison Prevention Week means pharmacy. From promotion of the Maryland Poison Center and its educational programs with posters and displays to giving presentations on poison hazards to schoolchildren, pharmacists throughout the state continue to play a tremendous leadership role in the success of Maryland Poison Prevention Week.

For Maryland Poison Prevention Week—1986, our educational focus will be on syrup of ipecac. The Maryland Poison Center encourages you as pharmacists to recommend that all parents of children under five obtain a one-ounce bottle of ipecac syrup for each child and keep it in their home. The Maryland Poison Center and the American Association of Poison Control Centers believe that when used according to label instructions and under the guidance of a qualified health professional, ipecac syrup is an essential part of effective poison prevention in the home. We concur with the American Academy of Pediatrics that one ounce bottles of syrup of ipecac should not be restricted to prescription status and oppose any unnecessary restriction on its availability including any "third class of drugs" status. Your help in counseling parents regarding the proper use and storage of ipecac syrup will be a major contribution to poison prevention week and to your patients. Posters promoting syrup of ipecac as well as our poison information card on syrup of ipecac will be available in February.

On March 17, 1986, the Maryland Poison Center will be one of two poison centers selected nationally to present a synopsis of its community poison prevention efforts at the 25th Anniversary of National Poison Prevention Week (NPPW) Ceremony and Conference at the Dirksen Senate Office Building in Washington, D.C. We would like to use this opportunity to highlight the efforts of the many individuals and organizations who have helped us to promote poison prevention week. If you have any slides or photographs that show participation in any poison prevention efforts, please send them with a brief description of the event and participants to Jacquie Lucy at the Maryland Poison Center 20 N. Pine Street, Baltimore, MD 21201 *no later than January 31, 1986*. All materials will be returned to you after presentation. If you have any questions about the NPPW ceremony or wish to attend, contact Jacquie at (301) 528-7184 or -7604.

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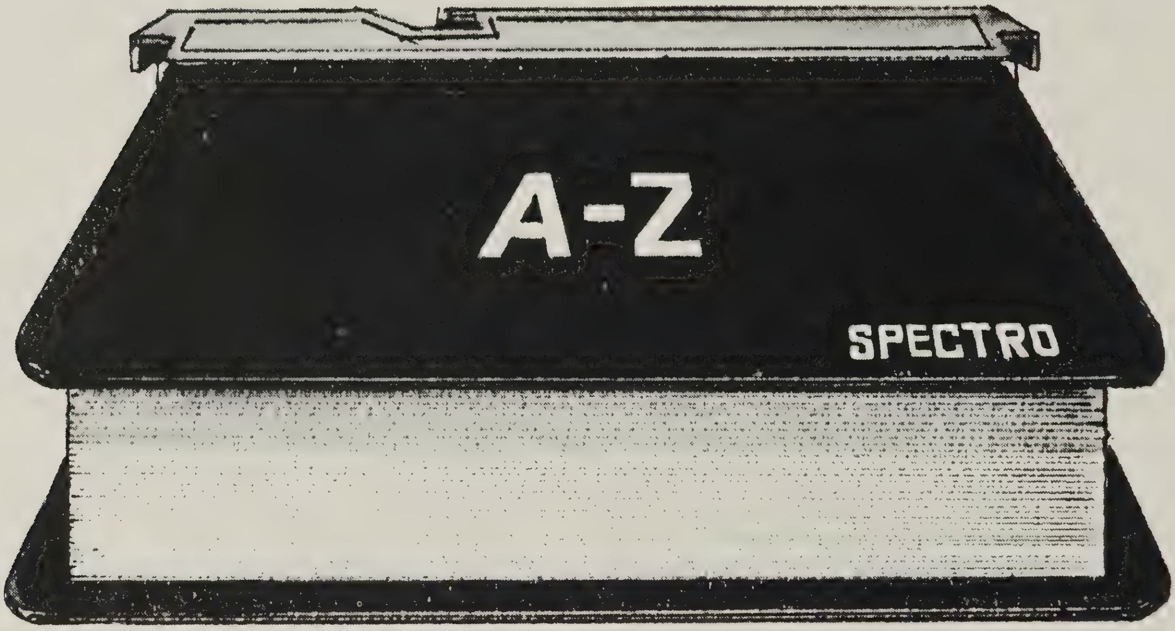

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DON'T LET THEM TELL YOU WHERE TO GO

Dear Pharmacist:

This is a "proof copy" sheet of the VITAL ISSUES bag stuffer provided to you by the MPhA. Keep this sheet clean, flat and unwrinkled, such as in a file folder.

This proof copy sheet enables you to make additional quantities of the bag stuffers which you should provide to all patients with third-party prescription coverage.

INSTRUCTIONS FOR USE: (1) take this proof copy sheet to rapid or instant print shop in your area; (2) have them run the additional quantity you require, **preferably in red ink on white paper;** (3) have them or you yourself cut out the four bag stuffers per page; and then (4) keep this proof copy sheet in your folder for future use.

The bag stuffers should be supplemented by discussion between The Pharmacists and patients on These Vital Issues.

Vital Issues you should know

$ $ $ $ $

PPOs, HMOs, mops . . . this alphabet soup affects you. It is the position of the Maryland Pharmacists Association that limiting your access to the pharmacy of your choice and mail-order prescription schemes are not in your best interest. Don't let them tell you where to go for pharmacy services, whether it be a PPO, HMO or mops.

Mail order drug programs are another instance of someone telling you where to go! Mail order prescription drugs may mean cheap drugs, but when you buy by mail here's what you're missing:

- Personalized service from the "drug expert"—your pharmacist—who knows which other drugs you may be taking that would interact dangerously with your new prescription and whether you might be allergic to the new medication.
- Your own "consultant," right there in the pharmacy to answer your questions about this medication and other non-prescription items you may want to use.
- Access to your pharmacist, in an emergency or on a 24-hour basis or even at home when you can't get to the pharmacy because of illness.

The next time your health plan describes the "benefits" of mail order prescription drugs, ask yourself these questions:

- What do you do until the medicine arrives in the mail?
- What do you do if the medicine is lost?
- What do you do if the medicine is stolen?

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PHARMACIST LEGEND

An Idea Whose Time Has Come

Pharmacist legend is the one issue that should unite the often disparate parts of the pharmacy world. Surely, pharmacists, OTC companies, and prescription drug manufacturers agree that reducing health care costs, ensuring the public safety, and providing consumers with greater convenience in obtaining drugs are goals we all should strive for. All are within reach if we can rally the component parts of pharmacy to support an interim pharmacist-legend stage of drugs.

First, however, some distinctions are in order. Pharmacist legend is *not* synonymous with a "third class of drugs." NARD does not advocate a permanent third class of drugs, but rather an interim stage of OTC drug marketing. A switched drug would remain pharmacist legend only for as long as it took the FDA to determine if there was imminent risk to the public health by letting the drug go fully OTC, and thus be available to all retail outlets.

A VIABLE CONCEPT

It is time to put the notion of a third class of drugs behind us. It has divided us for too long from the OTC drug industry. An interim pharmacist-legend stage is not only a viable concept, it is long overdue. But it will take a concerted effort on the part of national as well as state pharmacy associations to make the concept a reality.

NARD's advocacy of a "pharmacist-legend drug stage" is based upon three important goals: first, to reduce consumer health care costs; second, to increase consumer convenience; and third, to guarantee consumer protection. It is not NARD's intention to seek to change the status of those drugs currently available OTC nor to oppose the removal from prescription-only-status of appropriate drugs.

The concept of a pharmacist-legend drug stage was brought to national attention last year as the result of NARD's petition to FDA regarding the Rx-to-OTC switch of ibuprofen. NARD's efforts were directed at addressing a concern of an expert FDA advisory committee and giving FDA an opportunity to ensure consumer protection while, at the same time, allowing the drug to be more widely available to consumers. We were encouraged in these efforts by the support we received from a number of state pharmacy associations who, too, recognized that pharmacist legend was an issue whose time had come.

Just what is NARD advocating? The answer is quite simple. NARD is seeking a decision to be made by FDA, individually, on a drug-by-drug basis, that a health problem exists, that labeling is insufficient to address this health problem properly, that the public interest would not be served by restricting the drug to prescription-sale-only, that pharmacist counseling will address the problem properly, for an interim, transitional period until the health problem no longer exists, after which time FDA would decide that the drug could be made available for sale in all retail outlets.

WIDESPREAD ACCEPTANCE

Pharmacist-legend programs already enjoy widespread acceptance in Canada and the United Kingdom. We believe that our call for pharmacist legend in this country will benefit all parties concerned. Congress will benefit in that it will be assured FDA is protecting public health while restraining health care costs. FDA will be the beneficiary of an improved perception by Congress and by the public that it is performing its statutory mandate. The drug industry will be able to make prescription drugs more widely available, with assurance of consumer protection, at a lower cost to the consumer with increased profit potential. And the pharmacist will benefit by being able to utilize professional training while performing a valuable public service.

The primary beneficiary will be our patients who will be able to obtain these drugs at greater convenience and at less cost knowing that pharmacist counseling is available. The concept of a pharmacist-legend drug stage calls for an interim, transitional period wherein the FDA can make a proper determination whether a drug should move into general retail availability. In this way, there would be no repeats of the recent metaproterenol incident. Such a drug stage may also promote an even faster move of Rx drugs to OTC status.

NARD believes that pharmacist legend is clearly in the public interest. We will continue to work with other pharmacy organizations, consumer groups, and the drug industry to establish a pharmacist-legend drug stage. Your interest and support are invited, and needed, if we are to accomplish our goals of containing health costs and protecting the consumer.

FYI, a monthly perspective on topics of interest to pharmacists, is provided as a service by the National Association of Retail Druggists.

"Home Health Care—Pharmacy's Window of Opportunity"

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Panacea

I'm not unwillin'
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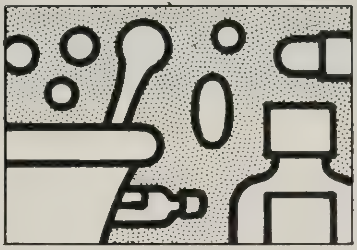
Whenever the Doc says I must.
But sometimes I wonder
If it's not a great blunder
In this cure-all forever to trust.

Be it fever of flu
or a running nose too,
He comes all prepared with a shot.
For an ache or a pain,
or a dull throbbing brain,
A cure in the needle he's got.

By Medical Lore
I set a great store,
And I'm not the one to be crabbin.
But it seems to me
that a Doctor to be
Had better start practicing jabbin.

Donated by Senior Citizen Morris Sackel at an Elder Ed Program.

Things You Should Know FOR YOUR GOOD HEALTH



Salt Terms to Look for on Labels

Heart diseases are the nation's number one killer. Hypertension, or high blood pressure, is often considered an accessory in many of those deaths. Salt, or sodium chloride, is believed to be a key factor in the development of high blood pressure.

Sodium is an ever-present element in the human diet, and although it's vital to good health and nutrition, most Americans consume more of it than they need. The National Academy of Sciences has recommended that Americans consume no more than three grams of salt per day. Estimates show Americans consuming 5-10 grams a day.

However, cutting down on table salt, the major source of sodium for most people, may not be enough. The sodium-conscious consumer must be knowledgeable and disciplined about the foods he or she eats. You must learn which foods are high and low in sodium. Take time while shopping in the supermarket to check food labels and ingredient lists for clues to sodium content. Know how to read a nutrition label and ingredient list. Sometimes a sodium ingredient is identified by its proper chemical name. At other times a general term is used, such as brine or salt pork.

Sodium is in most food and water either because it is a naturally occurring mineral element, or because it was added either during the manufacturer's processing or during the preparation of the meal at home. Most community water supplies contain varying amounts of sodium because it is naturally present or because it is added by the use of water softeners.

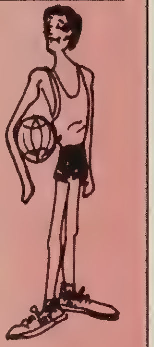
The following is a list of sodium terms to be aware of on labels:

Sodium terms to look for on labels
Sodium ascorbate
Sodium citrate
Baking soda
Sodium chloride
Sodium caseinate
Sodium acid pyrophosphate
Sodium phosphate
Sodium aluminum
Sodium bisulfite
Disodium phosphate
Sodium iron pyrophosphate
Sodium benzoate
Garlic salt
Calcium disodium EDTA
Sodium carboxymethyl cellulose
Monosodium glutamate (MSG)
Sodium preservatives
Trisodium citrate
Sodium aluminosilicate
Sodium stearoyl-2-lactylate
Sodium propionate
Sodium saccharin
Sodium tripolyphosphate
Sodium alginate
Disodium inosinate
Disodium guanylate
Sodium ferrocyanide
Sodium triosulfate
Celery salt
Sea salt
Disodium dihydrogen pyrophosphate
Sodium hexametaphosphate
Sodium gluconate
Sodium nitrite
Sodium erythorbate
Sodium nitrate
Baking powder
Anhydrous disodium phosphate
Sodium biphosphate
Salt pork
Brine
Dioctyl sodium sulfosuccinate
Onion salt
Sodium hydroxide
Sodium metaphosphate
Sodium thiosulfate
Flour (self-rising)

©State Pharmaceutical Editorial Association

national scene

Radically New Drugs



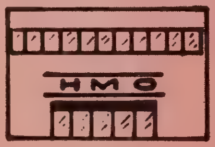
A new U.S. Department of Commerce report assessing the U.S. pharmaceutical industry projects several trends in the years ahead, including continued internationalization of the industry, increases in R&D and drug development costs, and growing pressures for health care cost containment. The report also predicts the emergence of radically new drugs in the future which will create a demand for more government regulation from all sides of the political spectrum. "Not only will these new drugs touch on the most personal and sensitive aspects of an individual's life and being (e.g., mental functions, reproductive systems, etc.), and hence raise special concerns for safety, but some will raise moral and societal issues that may be more far-reaching than current arguments concerning safety and efficacy," says the Commerce Department. An example of the kind of issues we may be facing, says the report, is a father's use of a new growth hormone—intended to combat dwarfism—to design a seven-foot basketball player son.

Physician Marketing

NEW HOURS!
OPEN
'TILL
9:00pm

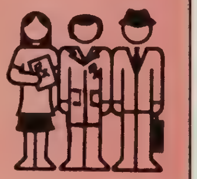
With 500,000 physicians in this country competing—among themselves and with other health professionals—for patients, more and more of them are turning to a variety of traditional, and not so traditional, marketing approaches. In the "tried and true" category are advertising of available services and sending out quarterly public-relations-oriented newsletters that offer patients information on such topics as treating the flu. More innovative efforts at attracting and retaining patients include keeping the office open longer—say, til 9 pm two days a week—and offering free care to anyone left among the old magazines in the waiting room for more than an hour. Similarly, pharmacists are going to have to focus additional efforts on making the consumer aware of the services they provide.

For-profit HMOs



Health care maintenance organizations (HMOs) are increasingly abandoning nonprofit status in favor of becoming profit-making companies, a new study by the Boston Consulting Group, Inc., declares. The report adds that, "along the way, some HMO managers are getting rich." At least 20 of the 115 nonprofit HMOs formed with Federal financing have converted to for-profit status, and, overall, some 85 of the nation's 311 HMOs are for-profit. While there is no data on the effect, if any, this development has on the quality of health care delivered, the for-profit HMOs have significantly higher costs and charge higher prices.

New Roles Ahead?



Despite the fact that the Federal government's Bureau of Health Professions has predicted that there will be an oversupply of pharmacists by 1990, several current trends suggest that pharmacists may, in fact, be able to capitalize on a variety of new roles and opportunities in the years ahead. Increasing numbers of pharmacists are already holding positions in nonpractitioner areas of employment—serving as association and company executives, government appointees, and regulatory personnel. Trends in the overall health care system will also affect the supply and distribution of pharmacists. The increase in the number of HMOs, the trend toward shortening the length of stay in hospitals, and the move toward home health care could mean there will be an even greater demand for pharmacists' services by the end of the decade.

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STATE JOURNALS SCORE WELL IN READERSHIP SURVEY

Members of state pharmacy associations more frequently read the state publications, such as the (*Maryland Pharmacist*) than they read national journals. In addition, state publications are perceived as having greater utility to the reader than national publications. These are among the findings of a readership survey recently conducted on behalf of the State Pharmaceutical Editorial Association (SPEA) of which the (*Maryland Pharmacist*) is a member. The survey was conducted by Dr. Paul Grussing, Professor of Pharmacy Administration at the University of Illinois College of Pharmacy, on behalf of SPEA.

A random sample of 510 pharmacists were surveyed from the sixteen states participating in the research. Over 275 pharmacists responded to the survey (55%). In an effort to determine the importance and utility of the state journals as compared to the national publications, respondents were asked their opinion on journal features, content and advertising.

Respondents were classified by current category of practice (institutional, chain, community, other) and by current position (staff, manager, other). Nineteen percent of the respondents practice in institutional settings. Fifty-six percent are managers, directors or owners. The mean age of respondents is 42. Respondents were also asked to indicate their membership in national associations. Forty-seven percent indicated they belong to their state association and one major national association.

Readership of the respondents' state journals was compared to that of eight journals having national distribution. Respondents indicated that they read their state journals regularly, reading most features in most issues. The most frequently read state journal features relate to new drug information, professional articles and legislative-political news. These highest ranked features compete with national journals in terms of content. These features also appear in the national publications, however, the study showed that the state journals are more frequently read.

Respondents were also asked to rate the usefulness of eleven content areas which were common to state and national journals. The two journal features perceived to be more useful when presented in state journals than in national publications were drug information and government news.

The "grass roots" value of state pharmacy association journals was clear from the survey results. Also emerging from the data is the finding that state journals have a firm hold on the readership of practitioners who have access to both national and state journals. The state journals excel in terms of frequency of readership and perceived utility to the reader.

The State Pharmaceutical Editorial Association (SPEA) is a cooperative group of 16 state pharmacy association publications. The group provides administrative and sales promotion support with regard to national advertising in the member journals and serves as a clearing-house for editorial material of common interest. Currently celebrating its fortieth anniversary, its offices are located in Chicago, Illinois. For more information contact Barbara A. Hogan, Administrative Manager, SPEA, 222 West Adams, Suite 400, Chicago, Illinois.

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The late Dr. Harry L. Schrader of Baltimore is the subject of a recently published book entitled "Mortar and Pestle, the World of Dr. Harry Schrader." His wife Mary (left) presented a signed copy to MPhA Executive Director David Banta recently at the Kelly Building. Ann Haris (right) wrote the book. Schrader contributed pharmacy artifacts to the B. Olive Cole Pharmacy Museum, the Smithsonian Museum and the Harper's Ferry Historical Museum. He retired from a community pharmacy located at Smallwood and Ramsey Streets in South Baltimore. Those interested in knowing more about the book may write to: Mortar and Pestle, P.O. Box 632, Riderwood, Maryland 21139

The Continuing Education Coordinating Council's program on "New Approaches to Infectious Diseases" was held November 10, 1985. Speakers (left to right) Karen Plaisance, Pharm.D.; George Drusano, M.D. and Wendy Klein-Schwartz, Pharm.D. and Program Chair, take a coffee break during the program.

The November 14, 1985 Maryland Society of Hospital Pharmacists meeting was held at Westminster Church, the site of Edgar Allen Poe's grave. Following dinner the subject of the meeting, appropriately enough, was "organ transplants."

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

KETOCONAZOLE:

The treatment of fungal infections has changed dramatically since the introduction of ketoconazole (Nizoral) to the general market. The drug has been used extensively and in some cases, indiscriminantly. Symptoms of hepatotoxicity have been reported associated with the use of ketoconazole, and thus physicians have been urged to limit the use of the drug to situations where it is the drug of choice. The toxicity associated with the antifungal drug is seen after eleven days of therapy and was noted to occur more often in women over the age of 40 years. *Br Med J,* Vol. 290, #6464, p. 260, 1985.

PROSTAGLANDIN-LIKE PREPARATIONS:

Two prostaglandin derivatives are being used experimentally to treat the symptoms associated with ulcer disease. Two agents have been used in clinical trials and the results of such trials indicate that these agents may have the potential of replacing histamine-2 antagonists in the treatment of gastrointestinal disease. G. D. Searle and Company is experimenting with misoprostol, a derivative of prostaglandin E-1 while Syntex Corp. is evaluating enprostil, a congener of prostaglandin E-2. Other prostaglandin derivatives which are being tested include trimoprostil (a prostaglandin E-2 derivative being studied by Hoffman-LaRoche, Inc.) risoprostil, a prostaglandin E-1 derivative of Ortho-Myers-Bayer, and abroprosil which may be marketed by Upjohn. Abroprosil is used experimentally via the intranasal route to control bleeding within the upper portion of the gastrointestinal tract. *JAMA,* Vol. 253, #5, p. 617, 1985.

LHRH:

Thirteen years ago a substance felt to be present, but yet unidentified, was finally isolated and its structure was determined. Subsequently an active molecule of luteinizing-hormone releasing hormone was synthesized thus proving the structure of the molecule. LHRH is postulated to be a product of the hypothalamus which causes the release of luteinizing hormone from the posterior pituitary gland. Identification and synthesis of the LHRH has allowed for the diagnosis and treatment of many conditions which had previously been refractory to therapy, including precocious puberty, cryptoorchidism, delayed puberty, hypogonadism, anovulation, secondary amenorrhea, the premenstrual syndrome, inadequate luteal function, endometriosis, acute intermittant porphyria and hormone dependent tumors. Many possibilities exist for the use of LHRH, its analogs and its antagonists. *JAMA,* Vol. 253, #4, p. 469, 1985.

ACETAMINOPHEN:

Acetaminophen (Tylenol) tablets were administered to patients and the progress of the tablet was monitored using fluoroscopy. When tablets were swallowed by the patient while in the supine position, travel down the esophagus was impaired and the overall bioavailability of the acetaminophen was decreased. In order to get maximal activity and absorption from a dose of acetaminophen, it should be swallowed with a large glassful of water while in a standing position. *Clin Pharmacol Ther,* Vol. 37, #1, p. 72, 1985.

DIABETIC DIARRHEA:

Diarrhea can be a serious complication of diabetes mellitus. Since enterocytes of the intestine seem to react to alpha-2 stimulation by promoting fluid and electrolyte absorption, and also inhibit anionic secretion, the alpha-2 agonist clonidine (Catapres) was administered to patients with the condition to see if a positive response might be obtained. Three patients with diarrhea resistant to conventional therapy responded in a beneficial way to clonidine therapy. *Ann Intern Med,* Vol. 102, #3, p. 197, 1985.

OPIATE RECEPTORS:

Separation of the mu-1 and mu-2 opiate receptors has been accomplished using a selective mu-1 antagonist, naloxonizine. This agent reverses the analgesic action of the narcotic without altering its effect on respiratory depression. It seems that the respiratory depressive effect of these analgesics is mediated through mu-2 activation and can be separated by using this selective antagonist. *J Pharmacol Exp Ther,* Vol. 232, #1, p. 149, 1985.

ERYTHROMYCIN SALTS:

Erythromycin has been used for a long time to treat disease conditions including chlamydial infections and Legionnaire's disease. Since the drug has been found to be unstable in gastric acid, it is administered either in a dosage form which prevents the antibiotic from dissolving in an acid medium or as an acid stable salt. A study was conducted in 24 volunteers which indicates that the amount of drug absorbed from a 250 mg tablet of erythromycin base was 5 to 7 times greater than that obtained from a 400 mg (as base) dose of erythromycin ethyl succinate, an acid stable salt of the antibiotic. The stability of the salt may be less than has been predicted. *J Clin Pharmacol,* Vol. 25, #1, p. 36, 1985.

QUINIDINE GLUCONATE:

Two products containing quinidine gluconate in sustained release dosage forms were compared to determine the time required to reach peak concentrations and the duration of action. Quinaglute Dura-Tabs by Berlex Laboratories were found to have a greater area under the curve and a greater concentration from 6 to 12 hours after administration of the drug than did a "generic equivalent" manufactured by Bolar Pharmaceutical Co. *Clin Ther,* Vol. 7, #1, p. 22, 1985.

VITAMIN C THERAPY AND CANCER:

A 1974 report raised the possibility that vitamin C may be useful in preventing the development of neoplastic growth in patients who had not been exposed to antineoplastic therapy. Later Linus Pauling joined in the support of vitamin C therapy for patients with the hypothesis that vitamin C enhanced the body's defense against these abnormal growths. Controlled studies have since shown that 10 grams of the vitamin per day did not have any effect over placebo therapy with regard to either the interval between the beginning of treatment and disease progression or patient survival. *N Engl J Med,* Vol. 312, #3, p. 137, 1985.

HYPERTENSION:

Although hypertension can be a continuous disease process, it appears that there may be methods of reducing or eliminating drug therapy in patients who have had their pressure controlled for a five year period of time. Patients participating in this experiment were found to have twice the chance of discontinuing medication for hypertension if they limited sodium intake and reduced their body weight. *JAMA,* Vol. 253, #5, p. 657, 1985.

The Student APhA Chapter at the School of Pharmacy requested that this response by their President to the "Strategic Plan" proposed by APhA be published for the membership in the Maryland Pharmacist. Here it is.

Dear Chairman Main and Board Members:

Presented at the Region II Midyear meeting was the Strategic Planning Proposal brought forth by APhA. The new proposals will dramatically change the structure of APhA and Student APhA.

There are some advantages in the proposal. One is that more students of pharmacy would be directly involved in APhA, seventeen additional students would become voting delegates to the APhA House. Presently there are 4 Executive Committee members, 8 Regional Delegates that serve on the Resolutions Committee, 8 Alternate Delegates that serve on the Reference Committee, 8 Regional Co-ordinators that organized the mid-year regional meetings, and 3 Delegates-at-large that follow APhA Policy Committees and serve in the APhA house (this does not include students that are appointed to Policy Committees, Nominations Committee, and other regional committees). All told there are thirty-one students involved nationally while only fifteen have votes in the APhA House. Overall the proposal would give Student APhA more representation in the APhA House but would not really increase student involvement on the national level.

According to the APhA Board of Trustees the changes would be beneficial to the students of pharmacy but in studying the proposal more closely we feel many detrimental effects may occur to the student group.

There would be less opportunity for students as a group to participate actively in the national association. There would be no chapter delegates and no use for student delegations to a national meeting. Since APhA votes by mail, the students would be forced to do the same and would lose their autonomy. Students need the opportunity to remain separate and work with their peers to develop leadership skills and a better understanding of the APhA system.

If students were admitted as full members a problem of "dilution through intimidation" may occur. The proposed plan to mix students and practitioners at regional and national meetings will abolish the students identity. The large amount of student involvement may decrease.

Student APhA affords us a "practice arena" that allows us to voice opinions among our peers without the fear of intimidation or making mistakes. Here in the "arena" leadership skills develop and students gain the confidence of expressing opinions which may contribute to the betterment of Student APhA and APhA. Without this "arena" many students may feel intimidated to express their opinion due to lack of experience compared with the vast experience of some APhA members. Students may also feel their problems and concerns will be "trivial" when compared to other problems of the profession. Pharmacy students need their own identity to practice and learn about the profession of pharmacy. The new APhA proposal will deprive student individuality.

With the present organization, once students graduate and join the APhA as full members, they are better equipped with the experience and confidence to face the challenges of the profession of pharmacy. We encourage you and the other board members to review and revise the proposed changes for the reasons discussed. We as students of the University of Maryland School of Pharmacy also need the individuality and experience provided by the Student APhA whether it be nationally, regionally, or at our own chapter.

Very Sincerely Yours,

Thomas P. La Martina
Chapter President Student APhA
Board of Trustees Member

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The Board of Directors of the Pennsylvania Society of Hospital Pharmacists approved funding for a full-time Executive Director. This new position will replace the existing part-time Executive Secretary which was created in 1980. Earlier this year, Mr. Herbert L. Flack, the current executive, announced his retirement to become effective in October, 1986.

After examining the progress of the Society during the past five years of having a paid executive, a special committee appointed to study the question recommended moving to a full-time Executive Director. Funding has been approved for a three-year contract commencing July, 1986.

Dr. Douglas E. Miller, Director of Pharmacy and Drug Information Service at the Hospital of the University of Pennsylvania has been appointed Chairman of the Search Committee. Applications are now being received at Society headquarters. Interested candidates may send a resume or curriculum vitae to:

Chairman, Search Committee
Pennsylvania Society of Hospital Pharmacists
43rd Street and Kingsessing Mall
Philadelphia, PA 19104-4495

POSITION AVAILABLE: The Nebraska Pharmacists Association is seeking qualified candidates for its Executive Director position. Applicants must have good management, organizational and communicative skills. Must be well-versed on important pharmacy and health care issues; a degree in pharmacy or other health profession is preferred. Send resumé and three references to: Nebraska Pharmacists Association, 600 S. 12th, Lincoln, NE 68508, by January 15, 1986.

The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Westview Mall Road Beltway Exit No. 15A. For further information contact President Frank Block (phone: 358-2743).

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RX LICENSE PLATES

Again this year, the MPhA will be making available a special line of license plates from the Department of Motor Vehicles for Pharmacist members of MPhA. A special one time fee of $10.00 per vehicle will be required and should be added to the fees specified by DMV. Mail the total check and forms to MPhA for processing. The tags will have the "RXA" prefix and numbers will be given on a first come—first serve basis. Watch for further details.

calendar

Jan 9, Thurs—MSHP Monthly Meeting
Jan 19, Sun—Alumni Association Dinner—rescheduled from Nov.
Feb 2, Sun—MPhA Mid Year Meeting, Annapolis Hilton
Feb 20–27—MPhA TRIP TO PUERTO VALLARTA, MEXICO. CALL OFFICE FOR SPACE
Mar 9, Sun—BMPA Dinner Dance—Bluecrest North
Mar 15–20—APhA Convention—San Francisco
June 20–22—MSHP Seminar, Ocean City
June 22–26—MPhA CONVENTION, SHERATON HOTEL, OCEAN CITY.

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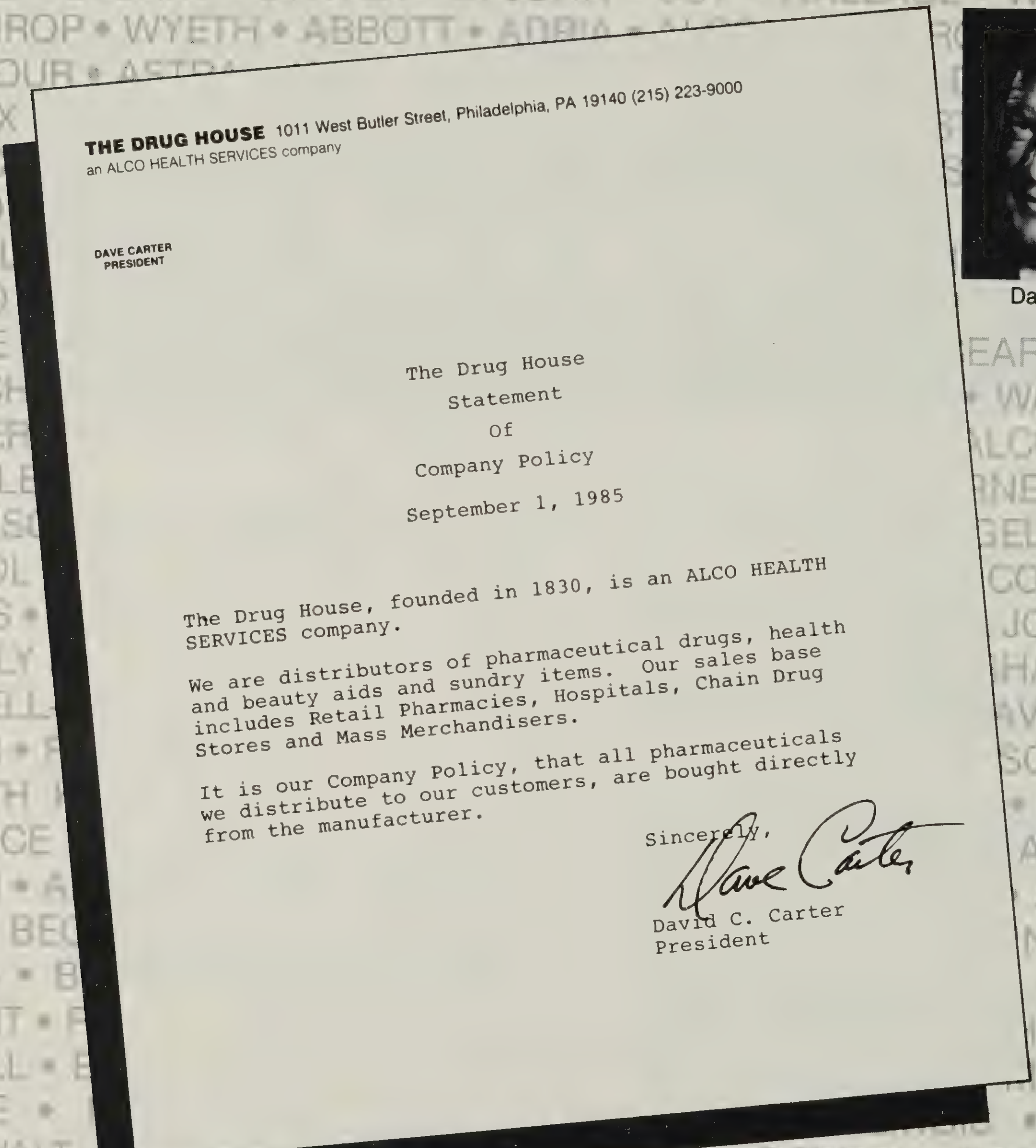

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February, 1986
VOL. 62
NO. 2

OTC Eye Preparations and Contact Lenses

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—*Thomas Gossel*

Continuing Education: A Better Way

—*Marvin L. Oed*

Impact of Liquor and Tobacco Sales on Community Pharmacy Operations

MPhA Lobby Fund Contributors List

Abstracts

THE MARYLAND PHARMACIST

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A CHALLENGING AND EXHAUSTING EXERCISE IN PLANNING FOR THE FUTURE . . .

Grassroots pharmacists, exemplary practitioners of unique abilities, will air views important to the continued viability of pharmacy as a profession at a working conference to be held May 2–3, 1986 in Alexandria, Virginia. The Maryland Pharmaceutical Association is co-sponsoring, with the Virginia Pharmaceutical Association, the first-ever practitioners' response to the findings of the Pharmacy in the 21st Century Symposium held in Millwood, Virginia in 1984.* Using the proceedings of the Symposium as a base, this conference will focus on disseminating information, eliciting response from participants and strategic planning for the future. Attendees will be invited from an eight state region (MD, DE, PA, VA, WVA, D.C., NC, KY) and should represent a cross-section of pharmacy practitioners from independent, chain, institutional and consultant practice. We are seeking the self-employed and employee pharmacists as well as those practicing in academia, government and industry. Our goal . . . to generate new thinking and to encourage participants to begin positive planning for the future.

INTERESTED? Attendance will be limited to approximately 15 practitioners from each state. This will be a ''working'' conference and we will require registration by March 1st to allow sufficient time for mailing the background materials. This meeting is participatory, not passive, and attendees will want to prepare for the workshop discussions. Continuing education credits will be offered. Please contact your state pharmacy association president (myself or Moe Delcher of MSHP) via phone or the attached form. We would be delighted to learn of your interest BEFORE March 1.

Madeline Feinberg
1985–86 PRESIDENT

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* An Executive Summary of the P-21 Conference was printed in two parts in the *Maryland Pharmacist*, October and November 1985.

GRASS ROOTS 21

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Registration will include a copy of the proceedings from ''Pharmacy in the 21st Century'' Conference (Millwood, Virginia—1984)

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SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 1

Advising Consumers On OTC Eye Preparations Part III: Contact Lenses

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Goals

The goals of this lesson are to:

1. discuss ocular problems that can be corrected by wearing contact lens;
2. compare contacts and spectacles, and hard and soft contact lenses.

in the service of pharmacy

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Objectives

At the completion of this lesson, the successful participant will be able to:

1. list the advantages and disadvantages of hard and soft contact lenses;
2. counsel the consumer on proper contact lens wear and care.

This is the third lesson in a series of articles on OTC eye care products. In the first two articles, the function of the eye and the proper use of OTC eye preparations were reviewed. In this lesson, we will discuss the background of contact lens solutions beginning with contact lenses themselves. Contact lens solutions and care products will be described in the following lesson.

The marketplace for contact lenses and solutions has become quite extensive. It is estimated that Americans currently spend in excess of $300,000,000 yearly on contact lenses and their care, half of which is spent on contact lens solutions. This figure is up over 50 percent from 1979. However, it is also reported that less than 60 percent of the total contact lens solution market is based on pharmacy sales. Since more than half of the approximately 15,000,000 contact lens wearers have soft lenses, and they spend $75.00 a year on the average for their solutions, the implications of providing a full line of products and counseling becomes quite evident.

Historical Background

Because there are major differences between the types of materials used in the manufacture of contact lenses and the types of solutions needed to care for each, we will first review the lenses themselves.

Even though the increased use of contact lenses is a recent phenomenon (approximately one-half of Americans need some type of eye correction and an increasing percentage of them now wear contacts), the concept is not new. Contact lens technology goes back to Leonardo da Vinci in the early 1500's. He theorized that emerging one's head in a large glass bowl of water could correct impaired vision. It is interesting to note that hundreds of years before the retina and its function were discovered, Leonardo drew pictures of errors in accommodation. It was his theory that people could not see clearly because the image of the objects they were looking at fell somewhere in front of or behind the eye. His idea never caught on possibly because while one can see better with one's head in a bowl of water, it makes for difficult breathing.

In the mid-1600's, a German physician reportedly used a lens to correct a refractory error by having his patients hold a tube full of water in front of their eyes. Glass spectacles followed soon after, but it wasn't until 1823 that someone suggested taking a mold of the cornea and placing a glass lens over it to correct vision.

In the late 1800's, an artificial eye maker manufactured the first glass scleral contact lens. From then until the 1930's, the few contact lenses made were produced by this long and tedious method of fitting lens after lens until the correct one was found. They were so heavy that very few people could tolerate them, especially since the tear fluids could erode them in about six months.

When plastics became available in the 1930's, the door for contact lens technology opened. It was an important breakthrough since a chemically stable, unbreakable, transparent and easy to work with lens was possible.

During World War II, an RAF surgeon noticed that pilots with pieces of shot-out plastic aircraft windows embedded in their eyes did not exhibit a foreign particle rejection antibody/antigen reaction. He and his associates were the first to develop the external hard contact lens as well as the artificial lens implant made of plastic.

More recently, soft plastic lenses, gas-permeable hard lenses, and extended-wear soft lenses have been developed. Each will be discussed in turn.

Sales of soft lenses now dominate the marketplace. It is reported that in 1982, soft lenses represented 71% of new fittings for contact lenses, and the percentage is still increasing.

Contact Lenses vs. Spectacles.

The answer to the question of which is better is largely a matter of personal opinion.

Most people who wear contact lenses agree that they have better and more natural vision than they do with spectacles. One distinct advantage of contacts is that however you move your eyes, you are still looking through the center of the lens. This does not occur with spectacles because light is coming through the cornea and the lens from all the different angles covered by the spectacle. Therefore, there is less image distortion with contacts.

Some prefer contact lenses because there are no frames to block peripheral vision, pinch the nose, head or ears, slide down a sweaty nose in warm weather, and fog up when there are changes in relative humidity. A major reason people prefer contacts over spectacles is that contacts are not visible to others.

However, not everyone can wear contacts. It is reported that there is a 15% rejection rate with hard lenses, but a much lower rate for the soft lenses.

Some individuals experience burning and redness due to the normal response of the eye to a foreign object. Others experience problems with excessive blinking which is a normal function of the eye trying to take care of itself by removing a foreign object. Others have problems with excessive tearing which washes the lenses out. Still others experience problems with the lenses falling out although this is more common with hard lenses than with the soft variety.

Some people are bothered by the glare of fluorescent lights and others develop photophobia. This is reported mainly with hard lenses. It may be corrected with the use of tinted lenses.

Two other potential problems with contacts are forgetting to take them out (one rarely does this more than once because it is quite painful to leave hard lenses in overnight) and lacking confidence in inserting and removing them. Another problem with the hard lenses is spectacle blur. Some individuals have trouble seeing after they take their hard contacts out, and the difficulty is not corrected by the use of their spectacles. This will be explained more fully later.

Contacts are difficult to wear for persons who have hay fever, rose fever or other allergies. Hormonal changes during pregnancy and the use of oral contraceptives alter the fluid balance of the cornea and interfere with the wearing. In some individuals, anticholinergics, antihistamines, tricyclic antidepressants, decongestants, and diuretics decrease tear secretion and interfere with lens wear. This will be discussed later.

One authority claims that brown-eyed brunettes with dark complexion are the easiest to fit with contacts, and the best wearers. Green-eyed, fair-skinned redheads are reported to be the hardest to fit and are most likely to discontinue using contacts. There are certainly numerous exceptions to this rule and the majority of people fall between these two groups.

The overwhelming majority of individuals who wear contacts prefer them over spectacles and would not go back to wearing glasses.

What Ocular Problems Do Contacts Correct?

The four major types of eye refractory errors were discussed in the first lesson of this series. To quickly review, **hyperopia** (farsightedness) is a refractive problem with the crystalline lens resulting from images being focused behind the retina. **Myopia** (nearsightedness) is the direct opposite in that the focal point of vision is in front of the retina. Either of these conditions may be corrected by hard or soft contact lenses.

Astigmatism is a condition in which the cornea does not have a perfectly spherical shape. Therefore, light rays entering through it are distorted. The less spherical the cornea is, the more blurred the vision. Since hard lenses are rigid, they will serve as a new sphere. Hard lenses can be used to correct nearly all degrees of astigmatism.

Soft lenses are flexible and cannot correct all astigmatisms. Until recently, they were rarely effective in correcting this condition. However, newer "toric" lenses are now available. There are two types of corrective curves, one for correcting nearsightedness or farsightedness, and another called a cylinder correction that takes care of the astigmatism. This form must be custom-made and is quite expensive.

Presbyopia (literally, "old vision") is a condition that requires bifocals. As we age, our lenses become stiffer and it becomes more difficult to focus on close-up objects. Presbyopia invariably results in the need for reading glasses. If the person is already nearsighted, bifocals are necessary with the upper portion used to correct distant vision and the lower for close-up vision.

Bifocal hard lenses have been available for some time. They have two major drawbacks. First, their fitting must be customized, a procedure which is long, arduous, and expensive. The second problem is that the up and down movement of the lens can be troublesome. When the person readjusts to the image, the distance changes and the object goes in and out of focus. However, some individuals wearing bifocal spectacles have the same problem.

The authors have a friend who wears trifocals. One day we asked, "How in the world can you see through those?" He said that he just moves his head up and down and whatever looks best, that's what he pays attention to .

There are two other solutions for correcting presbyopia without others knowing that you need bifocals. One is to wear contacts for far vision and half-glasses for reading.

Another concept that requires a great deal of motivation is based on the fact that bilateral organs have a dominant side. For example, some people are right-handed while others are left-handed. The same is true for vision. With **monovision**, the individual wears a lens on the dominant eye for far vision, and a different lens with a refractory power on the other eye for near vision. In a few weeks, the person learns to look at far away objects with one eye and to read close up with the other lens.

One major problem with monovision is that depth perception is difficult. Those who use this system (including a recent ex-president and renown network news anchorman) have two lenses available for the non-dominant eye. When good depth perception is needed, they remove the near vision lens and replace it with the one for distance.

Soft lenses are also used for correcting several other disorders. These include corneal dystrophy, keratitis (inflammation of the cornea), corneal ulcers, severely dry eyes and post-surgical healing.

Hard Contact Lenses

Hard contact lenses are manufactured from a plastic called polymethylmethacrylate (PMMA). It is a material quite similar to Plexiglas® and Lucite®. Hard lenses retain their shape in or out of the eye, and they take on very little water.

The term "contact" lens is really a misnomer for hard lenses because they do not actually make contact with the eye. Hard lenses and the cornea are hydrophobic so the lens floats on a layer of lacrimal and ocular secretions over the top of the cornea without touching it. A major difference between hard and soft lenses is that the former can be no larger than the cornea. If they were larger, there would be inadequate transfer of fluids between the cornea and the lens, and inadequate oxygen to the cornea.

The cornea is unique in that it is not directly supplied with blood vessels. Therefore, the cornea does not receive oxygen directly from the blood; instead it is nourished by the aqueous humor, various other tear secretions, and to a small extent, from the atmosphere.

Hard lenses block out oxygen that normally enters the cornea osmotically from the air. Therefore, when they are worn, the cornea must rely on tear flow. The eyelid accomplishes this in two ways. First, each time the eyelids close, they press down slightly on the contact and force out the "old tears" that were underneath. When the eyelids open, the contact rises slightly and pumps in "newer" tears.

Second, the lids cause the contact to rotate, reportedly one full rotation every six to ten blinks. This "whirlpool" action brings in more tears. Individuals who wear contacts must blink at least five times a minute to provide adequate oxygen and to lubricate the eye.

In summary, the hard lens is a tough, acrylic disc, smaller than the cornea, that is hydrophobic (water-repellant). Soft lenses are flexible discs that are larger than the cornea and are hydrophilic (water-seeking).

Soft Contact Lenses

There are several kinds of soft contact lenses made from a variety of chemicals. One of the more commonly used plastics is hydroxyethylmethacrylate (HEMA).

Soft lenses are flexible, absorb water, and conform to the shape of the eye. Many of them have a water content exceeding 50 percent. Earlier, we related the hard lenses to Plexiglas™ and Lucite™. Soft lenses are more like Saran Wrap™ or Handiwrap™.

Soft lenses adhere directly to the cornea through hydrophilic capillary attraction. They must be larger than the cornea and fit slightly underneath each eyelid. If they were smaller than the cornea, the lenses could fall out with one blink.

Soft lenses are manufactured in a manner similar to hard lenses. They are lathe cut from polymer buttons, molded into a spherical shape, and hydrated in hot saline solution for several days. In this procedure, they swell to the proper size and impurities are extracted. To maintain their shape, soft lenses must always be kept in an isotonic solution, both before and after fitting.

Another major difference between hard lenses and soft lenses is that the former must be form-fitted to each individual's corneal shape. This may require several days. Although soft lenses differ in their refractory power, "a few sizes fit all." Once the refractory power is determined, soft lenses can be selected off the shelf and fitted into the eye immediately.

As stated earlier, soft lenses must be hydrated at all times and stored in an isotonic solution. If the solution is hypotonic, the lens will swell. If it is hypertonic, the lens will shrink. In either instance, they will be less comfortable on the eye. The pH is a factor for some lenses because certain plastic polymers will shrink if the pH is below 6 and swell if it is above 6.

Because they contain many hydroxyl, carboxyl and lactam groups, all of which are chemically reactive, soft lenses can be ruined by absorbing chemicals. Therefore, it is unwise to self-medicate with eye drops not specifically labeled for use with soft contact lenses. In many instances, both the preservatives and the active ingredients will bind with the soft plastic material. This is especially true of epinephrine and phenylephrine which can actually turn the lenses brown.

The irrigation and soaking solutions for soft lenses contain a low concentration of preservatives. If they are soaked in the more concentrated solutions used for hard lenses, soft lenses can take up the preservative and release it into the eye leading to irritation.

The water in soft lenses can evaporate if the lenses are left out of solution for any length of time. It they become dry, they can be ruined. Rehydrating a dry lens is difficult, and the individual must closely follow the manufacturer's instructions.

The water content in soft lenses can also evaporate in excessively low relative humidity, when there is inadequate tear production, under the hair dryer, in high winds, or in dry climates. When the lenses begin to dry, they shrink and tighten on the cornea, thereby irritating the eye and causing blurred vision.

Hard Lenses vs. Soft Lenses

There are pros and cons for both hard and soft lenses. They are compared in Table 1.

Those who prefer hard contact lenses claim that they are less expensive, more durable, easier to get in and out, and easier to take care of. In most instances, soft lenses are more expensive than the hard ones. The average life of a soft lens is one and one-half to two years (they tear easily), whereas hard lenses may last twenty to thirty years. The daily care of soft lenses is more time consuming, and the solutions more expensive than those for the hard variety.

Proponents for soft lenses counter these claims by stating that the softs are easier to fit, are more comfortable, and allow for better peripheral vision. They can also be worn "on and off" and do not cause spectacle blur.

TABLE 1
Differentiation of Hard and Soft Contact Lenses

Hard	Soft
Composition	
tough, acrylic disc	flexible disc
smaller than cornea	larger than cornea
hydrophobic	hydrophilic
Indications	
astigmatism	aphakia
color blindness	astigmatism
farsightedness	eye bandage
nearsightedness	farsightedness
	nearsightedness
Advantages	
easier to get in and out	easier to get used to
easier to take care of	more comfortable
more durable	can wear "off and on"
tintable	no spectacle blur
less expensive	better peripheral vision
	easier to fit
Disadvantages	
take longer to break in	takes longer to care for
pop out more easily	more expensive
don't always follow eye movement	cannot be marked right or left
become scratched and warped	absorb chemicals
Solutions	
wetting	cleaning
cleaning	disinfecting
soaking	chemical
lubricating	thermal
combinations	lubricant

Wearing soft lenses "on and off" means that the wearer does not have to readjust if they aren't worn for awhile. This is not true for hard lenses. After being properly fitted, a hard contact lens wearer must gradually increase wearing time over a period of days until he can tolerate them for ten to twelve hours per day. Generally they can be worn four hours the first day, and wearing time can be increased an hour a day thereafter.

Hard lenses cannot be worn overnight as stated earlier. Even though well-fitted hard lenses serve as a pump for tears and each blink of the eyelid brings in new tear fluid that is rich in oxygen, they cannot accomplish this indefinitely. After several hours, the amount of available oxygen for the corneal cells is diminished somewhat and the cells begin to swell. This leads to corneal edema which makes the contact uncomfortable. Highly motivated individuals can manage this. Others cannot.

A bothersome effect for some hard lens wearers is **spectacle blur**. This is a blurred, hazy vision due to swollen cells in the cornea after a number of hours of lens wear. In some individuals, it takes awhile (sometimes overnight) for eyesight to return to normal. For these individuals, the wearing of regular spectacles does not correct the problem. If hard lenses are worn throughout the day, it is difficult to watch television with spectacles.

Even though hard lenses pop out more readily than soft lenses, they are easier to find, clean, and replace into the eye. Hard lenses can be marked "right" or "left," whereas soft lenses cannot be so designated. The hard lens for the right eye has a small black dot that does not interfere with vision. If soft lenses get mixed up, it is difficult to determine which is for the right eye and which is for the left.

Gas-permeable and Extended-wear Lenses

An indepth discussion of these lenses is beyond the scope of this article. Basically they differ from hard and soft lenses in that they can be worn longer.

The **gas-permeable** lenses are similar to hard lenses since they are about the same size, but they are more flexible. Their major advantage is that they allow the transfer of oxygen freely from either side of the lens to the other. They are composed of a plastic called cellulose acetate butyrate (CAB), or a combination of PMMA and silicone.

Gas-permeable lenses are just as durable as hard lenses, but more wetable. They are especially suited for those who cannot tolerate the standard hard lenses but have a vision problem that is not corrected by soft lenses.

The **extended-wear** lenses represent a more recent development. They are made of varying copolymers of HEMA and other hydrophilic plastics. Most of them consist of a three-dimensional network of copolymer chains joined together by cross-links of chemical bonds. They find extensive use in persons who have had cataracts removed.

Cataracts are more than simply a film that forms over the eye. The crystalline lens is normally transparent. But with age, illness or injury, the lens develops areas of opacity due to precipitation of foreign materials within the lens. This leads to a cloudiness in vision because it blocks light from reaching the retina.

Cataracts can be removed surgically to restore eyesight. The term aphakia refers to the absence of the lens of the eye. If enough is removed, however, it becomes extremely difficult to see close-up. There are three procedures to correct vision after cataract removal: wearing thick, heavy, uncomfortable glasses, having an artificial lens implanted, and wearing contact lenses.

While there is some controversy on the subject, the artificial lens implant, barring complications, is often best because it allows full correction of vision when used with regular glasses. In this procedure, the natural lens is replaced with a plastic implant. It is much more convenient to care for than contacts. Critics say the procedure is too risky and if the lens is defective or becomes contaminated, the patient must return to surgery. However, the FDA Advisory Panel on Ophthalmologicals has stated that the benefits of the artificial lens implant exceed the risks.

The third method for restoring eyesight after lens removal is wearing extended-wear contacts. It is claimed that they provide vision equal to an artificial lens. If anything goes wrong, the contact lenses can be removed. The biggest disadvantage is that the patient's close-up vision may be so bad that he cannot see well enough to insert or remove the contact lenses.

Elderly people have even more problems with contact lenses due to loss of manual dexterity. Extended-wear soft lenses are beneficial because they only need to be removed and cleaned every two weeks or even less frequently. A list of "do's and don'ts" for the care and wear of various types of contact lenses is presented in Table 2.

TABLE 2
Do's and Don'ts for Contact Lens Care and Wear

I. Do's
- Wash and rinse hands thoroughly before handling lenses.
- Follow recommended procedures for lens hygiene daily.
- Adhere to your practitioner's instructions and wearing schedules.
- Avoid harmful and irritating vapor and fumes.
- Use extreme care when inserting or removing lenses to avoid scratching the eye with the lens or fingernail.

cont.

TABLE 2 Cont.

- Always work with one lens first to avoid lens mix-up.
- Keep lenses and storage case clean at all times.
- Wear quality nonprescription sunglasses outdoors.
- Contact your eye specialist immediately if you have difficulty.
- Tell your other doctors that you wear contact lenses.
- Have eyes and lenses checked periodically.
- Tell your doctor before using medications in the eye.

II. Don'ts

- Scrape lenses over any hard or rough surfaces.
- Allow soft lenses to dry out.
- Expose lenses to extreme heat.
- Swim with lenses in.
- Rub lenses with cloth, tissues, cotton, or paper lens cleaners.
- Try to pick up lenses with tweezers or any other utensil.
- Clean lenses with household detergents, chemicals or cleaning fluids.
- Use saliva to wet lenses.
- Lean over an open sink while inserting or removing lenses.
- Sleep with contact lenses on the eyes.
- Rub eyes or eyelids while wearing contact lenses.
- Use aerosol products such as hair sprays when wearing lenses.

III. If You Notice These:

- eyes sting, burn, or itch (irritation)
- comfort is less than when lens was first placed on your eye
- feeling of something in the eye (foreign body, scratched area)
- excessive watering (tearing) of the eyes
- unusual eye secretions
- redness of the eyes
- reduced sharpness of vision (poor visual acuity)
- blurred vision, rainbows, or halos around objects
- sensitivity to light (photophobia)
- dry eyes

Do This:

- Remove your lenses.
- If the discomfort or problem stops, then look closely at the lens.
- If the lens is damaged, DO NOT put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse, and disinfect the lens; then reinsert it.
- If the problem continues, DO NOT put the lens back on your eye but IMMEDIATELY consult your eye care practitioner.

'Tween Scripts

By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.

Pharmacy's One World

As pointed out by Mr. Desmond Lewis, Secretary and Registrar of the Pharmaceutical Society of Great Britain, during his lecture to 1985 recipients of the A. H. Robins "Bowl of Hygeia" Award in October, the relative ease of reciprocity in our country is a benefit which most pharmacists take for granted. This is not the case in other areas of the world. It has only been a few months since the Government of Europe, which is located in Brussels, issued directives which require the 10 nations comprising the European Community to begin removal of existing restraints on the ability of pharmacists to move freely between member countries and to standardize educational requirements which presently vary from a seven-year qualifying course for a pharmacist in Holland to a two-and-a-half-year course in Germany. The challenge will be to achieve a uniform standard of education which does not lower current practice standards. Mr. Lewis went on to describe the even greater challenges which our profession faces in the 48-member Commonwealth of Nations. A free association of sovereign states, all of which were at one time part of the British Empire, the Commonwealth is comprised of six developed countries, and the rest are what are called Third World or Developing Countries.

Most Third World countries have no means of distributing medicines to their people because they have no pharmacy profession. One African country, Malawi, with its population of 6 million, has four community pharmacies and a total of 23 pharmacists. The country has 80 medical practitioners and health services are generally provided by medical assistants trained in a two-year course.

The status of the profession in countries such as Malawi will surely influence its status in other developed and developing countries and in Europe. This ripple effect will inexorably reach our own shores. As Pharmacy's One World continues to shrink, the status of the profession in countries both near and far will increasingly influence our own practices. We must give such issues and their possible consequences a fair measure of our time and consideration.

Jake Miller

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CONTINUING EDUCATION: A Better Way

by Marvin L. Oed, Pharm.B.S.

Introduction

The formal pharmacy educational process can prepare one to function adequately as an entry level practitioner. Most pharmacists would probably agree that an effort toward increasing competence beyond that point requires on-going self-education. If the self-education process does not start shortly after graduation it becomes more and more difficult to begin (even as the practitioner becomes less and less competent). The habit of putting educational activity off until "later" can develop all too easily as other priorities and distractions seem to postpone these efforts. However, the majority of, if not all, pharmacists read one or more professional journals. Reading journals can be a very effective learning method provided that the pharmacist selects and reads journals and articles critically. This method of self education is unstructured and therefore requires the pharmacist to become compulsive about reading. Formal continuing education programs have been developed in an effort to meet perceived practitioner self-educational needs. Not all of these programs are equally successful. This article discusses the various characteristics of effective programs and suggests one format that should be used by organizers of continuing education programs.

Continuing Education Programs

Continuing education programs provide a structured format for maintaining and upgrading professional competency and skills. Programs have been developed by drug companies who then offer CE as a service to the pharmacy profession. Pharmacy schools and professional organizations offer CE programs. Finally, there are also proprietary organizations who provide CE. A number of these CE providers offer many programs on various topics using a variety of ways, such as professional journals, professional meetings, inservice programs, and video and audio tapes. Most programs must, in order attract a large audience and to be cost effective, be designed for participants that may have a wide background of education and experience as well as diverse needs and desires. It is very difficult to be all things to all people and achieve excellence simultaneously.

CE programs for practitioners should differ from traditional academic educational programs because of the nature of the audience. Undergraduate students typically are taught *what* they need to know in order to practice their profession. Practitioners need to be taught *how* to integrate their knowledge with practice. A successful CE program must not only provide information but also instruct the participants in how to utilize the information presented to make some change in their practice.

My experience in continuing education as a participant, as a presentor, and as a member of the Continuing Education Coordinating Council has shaped my preception of what constitutes an ideal CE program. My feeling that there is a need for more emphasis on practical applications has been confirmed by pharmacists, other health professionals and educators. Recently, I conducted an informal survey by asking several pharmacists leaving a CE program three questions:

1. Did you like the program?
2. Did you learn anything new?
3. What changes are you going to make in your practice as a result of what you learned?

Their responses were typically:

1. "Yes, I liked the program". (And, in fact, they felt that the presentors were very knowledgeable and were good speakers)
2. "Yes, I learned a great deal". (They felt that quite a bit of "new" information was provided).
3. I received a few blank stares to this question and one pharmacist mumbled something to the effect that, "I'll be more aware of the elderly". (The program was directed toward the pharmacist's role in caring for the elderly)

The program receives good evaluations from the participants. Nonetheless, I find it distressing that after all the effort organizers and presentors expended, no one (at least among those interviewed) came away with a potential practice change in mind. Unless increased knowledge results in practice change, the time spent in acquiring that knowledge is wasted. To effect a change in practice, CE programs must concentrate more on what pharmacists need to *DO* rather than what they need to *KNOW*. This article recommends numerous changes to enable CE programs to concentrate on what pharmacists should do while simultaneously increasing their level of knowledge.

A Model CE Program

To be successful a CE program should:

a. have broad appeal,
b. meet the educational needs of practitioners with a variety of educational and experiential backgrounds, and
c. demonstrate practical applications of the topic addressed.

A specific design for a program that would meet the above criteria is outlined below.

Design

There are three elements in the design of this model program:

1. Needs Assessment
2. Pre-Program Preparation
3. The Program

Needs Assessment

The purpose of the Needs Assessment is to gather information from the potential audience before the program so that this information can be used in the program design. A sampling of practitioners are surveyed to determine topics of interest and, equally important, the audience's perceived weaknesses and needs. Too often a CE program is based upon what the presentor wants to teach and not on what the participants want to know or need to learn. Thus, the program developed in such a manner may teach over the heads of some of the audience and down to others. If the program attempts to bring "everybody up to date" there may be little time for anything else. The alternatives are to present the material at a low level of sophistication (rendering it valueless for those who have kept up) or teaching at a higher level (beyond the basic understanding of some participants). Either way a portion of the audience is lost. My experience is that many programs seem to do some of each. Consequently they have something to offer to each group but not a great deal to either. A properly designed needs assessment will provide the framework for developing a program that addresses specific issues that were identified by the potential participants.

Pre-Program Preparation

The needs assessment is used by the CE organizers to determine what areas practitioners perceive should be addressed. Prior to the scheduled date of the program participants are provided information to bring everyone to the same basic level of understanding of the topic. This will be in the form of reprints of journal articles, appropriate CE articles, especially designed materials, or a combination of these. Since the participants will be prepared prior to the program learning can begin at a higher level thus increasing the effectiveness and efficiency of the program.

By providing background material well in advance each participant can proceed at his/her own pace, paying particular attention to new information while expending little effort on that which is already familiar.

The Program

The actual program will differ little from existing programs except that the content will be directed more toward what the practitioners should *DO* rather than what they should *KNOW*. What they need to know will have been provided in the pre-program materials. In other words, the program emphasises the application of the material. Based upon this type of approach it would seem that small group or workshop formats would tend to increase.

This type of approach places additional burdens on the organizers of continuing education, but hopefully with increased benefits to both the audience and presentor.

Summary

This approach is unique in two ways. First, the two part format differs from the traditional approach. Second, it offers advantages to virtually every one involved: organizer, presentor and participant. The information provided by the needs assessment make it easier to design the program, develop goals and objectives and select presentors. The presentors will have accurate information about the needs of the audience and therefore be able to direct their presentation toward meeting specific those needs. The greatest benefit will be to the participants since the program will meet needs that they themselves identified. Participants will be prepared to begin learning immediately upon the start of the program. (In fact the learning process will have begun before the program because of the pre-program information).

In conclusion the following points need to be considered by the organizer:

1. Advanced preparation is required in order to complete the needs assessment and design the program.
2. The Pre-program materials must be developed and distributed.
3. The program must be advertised well in advance to allow time to register the participants and distribute the pre-program material and still allow time for the participants to review the information.
4. There will be additional time and expense involved in data collection and the distribution of the extra materials.
5. An examination will need to be administered and evaluated if additional CE credit is to be awarded for pre-program participation.

Perhaps most important and not addressed by the article is that patients will benefit because the participants will be able to make practice changes that could result in improved health care.

An example of a program using the suggested design will be offered by the Continuing Education Coordinating Council on May 12, 1986. The details of this program "The Role of the Pharmacist in Diabetes Patient Management", are found elsewhere in this issue.

School of Pharmacy/Continuing Education Coordinating Council Offer Unique Diabetes Program

"Diabetes, The Role of the Pharmacist", if the first program to be presented under a unique format that is suggested by the article appearing elsewhere in this issue. To meet the program objectives emphasis will be placed on how pharmacists can utilize their knowledge to improve diabetic patient care. Ample opportunity will be provided for practitioners input in the small group and workshop sessions. This will enable participants to develop their own methods to integrate the information presented in their practice.

Those completing the full day program will receive 5.0 CEU. Those who elect to complete the optional examination provided with the pre-program materials will receive an additional 1.0 CEU (total 6.0 CEU). Early registration is essential to allow unhurried completion of the pre-program material and optional examination. Although the pharmacist sampling has occurred suggestions are still solicited and should be submitted to Marvin Oed at the School of Pharmacy (528-7118).

LETTERS

Dear David,

I am again a member of the annual seminar committee for the MSHP. Therefore, I am again writing to you to announce this years upcoming annual seminar. This year we will be returning to one of our favorite sites, Ocean City, Maryland. We would like to announce our seminar in the upcoming Maryland Pharmacist Newsletters. The following information we would like to include

Event: Maryland Society of Hospital Pharmacists Annual Seminar
Date: June 20–22, 1986
Site: The Carousel Hotel, Ocean City, Maryland
Contact: Paul Jeffreys, Department of Pharmacy Services, University of Maryland Medical System, 22 S. Greene Street, Baltimore, Maryland 21201 (301)528-5650

The speakers are still being contacted and more will be forthcoming. Thank you for your time and assistance in this matter.

Sincerely,
Mark G. Click, P.D.

Dear Dave:

During the past decade, we have seen dramatic changes in the practice of pharmacy. In the name of "cost containment," the third party prescription administrator tells us what we are to dispence and the fee they will pay for the service. The inability to negotiate effectively with a third party vendor has provided a "take it or leave it" attitude in so far as the fees that we are paid. Mail order prescription firms are flourishing and major HMO and third party administrators are considering mail order prescriptions as a less expensive alternative for their clients.

This erosion of the pharmacists' professional and economic welfare must cease. As dedicated and effective as David Banta and his legislative team have been in holding the line in the bombardment against our profession, the suggestion by the MPhA that we hire a professional lobbyist has much merit, and I urge my fellow pharmacists to make the requested investment of $20.00 in the future of our professional life.

But we must do more—pharmacists must become more politically active. I urge you to join me in running for the legislature in 1986. Only a small margin of votes prevented me from defeating an incumbent in the last primary election, and with a greater effort, it is my hope that the result will be different this time.

As pharmacists appealing for legislative relief, I don't think of us in the same manner as just any special interest group. The very survival of our profession is at stake. Time is of the essence. We must act promptly.

Yours truly
Don Elliott

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The Impact of Liquor and Tobacco Sales on Community Pharmacy Operations

Over the years, it has been suggested by retail pharmacy practitioners that low-margin goods such as liquor or tobacco are a necessary part of the overall merchandise mix in community pharmacies. They indicate that these products help support an attractive buying environment for patrons which, in turn, increases customer traffic. The overall impact of these sales on profitability has not been evaluated but was assumed to be favorable.

This study attempts to quantify the influence of liquor and tobacco sales on selected operating statistics and profitability. Data for the study were submitted by contributors to the 1984 *Lilly Digest*.

TABLE 1
Lilly Digest Liquor Study
(as a percent of total sales)

Averages per Pharmacy	Liquor Income Under 5% of Sales (40 Pharmacies)	Liquor Income Over 5% of Sales (43 Pharmacies)
Total Sales	$619,290—100.0%	$830,412—100.0%
Cost of Goods Sold	70.4%	71.9%
Gross Margin	29.6%	28.1%
Total Wages	14.8%	14.5%
Rent	2.2%	2.3%
Total Expenses	27.0%	27.1%
Net Profit	2.6%	1.0%
Pharmacy Hours Open per Week	69	72
Floor Area (sq. ft.)	2,785	3,864
Prescriptions Dispensed Annually	30,358	25,341
Prescription Sales Share of Total Sales	55.2%	34.6%

Table 1 shows that when liquor sales activity surpasses 5 percent of total sales, the cost of goods sold increases, which results in a decreased gross margin as a percent of sales. Total wages are lower, whereas rent is slightly higher, percentagewise, for these stores when compared with pharmacies having a smaller share of liquor sales. The total expenses figure was similar for both groups of stores. Since gross margin declined and total expenses were about the same, net profit declined from 2.6 percent to 1.0 percent of sales as liquor sales activity increased. As expected, the higher-liquor-share stores posted higher total sales, were open longer hours, and had a large floor area. It is interesting to note that a review of prescription activity in these retail drug outlets indicates that as liquor sales increase, there is a reduction in the number of prescriptions dispensed annually and a substantial decline in the share of prescription sales to total sales.

This scenario suggests that high-liquor-share stores may be merchandising-type operations. Further, higher-liquor-sales activity was not associated with greater annual prescription volume or improved profitability. The optimum mix of liquor sales to total sales appears to be under the 5 percent level.

The operating statistics for pharmacies reporting tobacco sales show a similar operating profile. As seen in Table 2, total sales volume tends to rise as tobacco sales share advances. The cost of goods sold for these drugstores increases as the proportion of tobacco revenue rises to bring about a reduction in the gross margin figure. As a percent of sales, total wages decline and rent tends to move up slightly, which causes total expenses to fall evenly as the share of tobacco sales increases. These economies of scale were not sufficient, however, to offset the declining margin, with the result that net profit showed a steady downtrend. However, this declining trend was not as pronounced as that of the liquor group. Pharmacy hours open per week and total floor space advanced as the share of tobacco sales grew. This is consistent with the trend observed in the liquor portion of the study.

It is noteworthy that prescription activity tends to rise as the percent of tobacco sales to total sales increases until the highest category—over 6 percent. However, it should also be noted that the prescription sales share of total sales declines significantly as tobacco revenue advances. These data suggest that the expansion of the tobacco department seems to be more a function of the merchandising nature of the operation than a planned management action. Surely, management would opt for the better profitability associated with a larger share of prescription activity.

A review of the net profit profile in the tobacco portion of the study indicates that net profit is not seriously affected until the mix of tobacco sales to total sales exceeds 3 percent; and that optimum profitability will probably be realized when tobacco income is less than 1 percent of total sales volume.

In summary, this study suggests that for optimal profitability, the sales mix of these two departments should be under 5 percent of total sales for liquor and under 1 percent of total sales for tobacco.

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—$.02 per coupon; 500 to 1000 coupons—$.02.5 per coupon; and batches of 1000 coupons and over—$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.

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30¢ OFF
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SAVE ON OLD EL PASO TACO SHELLS
IVE 20

Call Mary Ann at the MPhA office (301-727-0746) to receive details by mail and your first mailing packet.

TABLE 2
Lilly Digest Tobacco Study
(as a percent of total sales)

Averages per Pharmacy	Tobacco Income Under 1% of Sales (152 Pharmacies)	Tobacco Income 1% to 3% of Sales (70 Pharmacies)	Tobacco Income 3% to 6% of Sales (76 Pharmacies)	Tobacco Income Over 6% of Sales (125 Pharmacies)
Total Sales	$499,458—100.0%	$659,257—100.0%	$686,585—100.0%	$685,411—100.0%
Cost of Goods Sold	65.3%	66.5%	68.8%	70.7%
Gross Margin	34.7%	33.5%	31.2%	29.3%
Total Wages	17.4%	17.1%	16.4%	15.1%
Rent	2.1%	2.2%	2.3%	2.3%
Total Expenses	31.1%	30.5%	28.9%	27.4%
Net Profit	3.6%	3.0%	2.3%	1.9%
Pharmacy Hours Open per Week	60	66	69	71
Floor Area (sq. ft.)	2,660	2,859	2,928	3,121
Prescriptions Dispensed Annually	28,513	30,811	31,386	28,138
Prescription Sales Share of Total Sales	62.0%	52.7%	48.7%	44.0%

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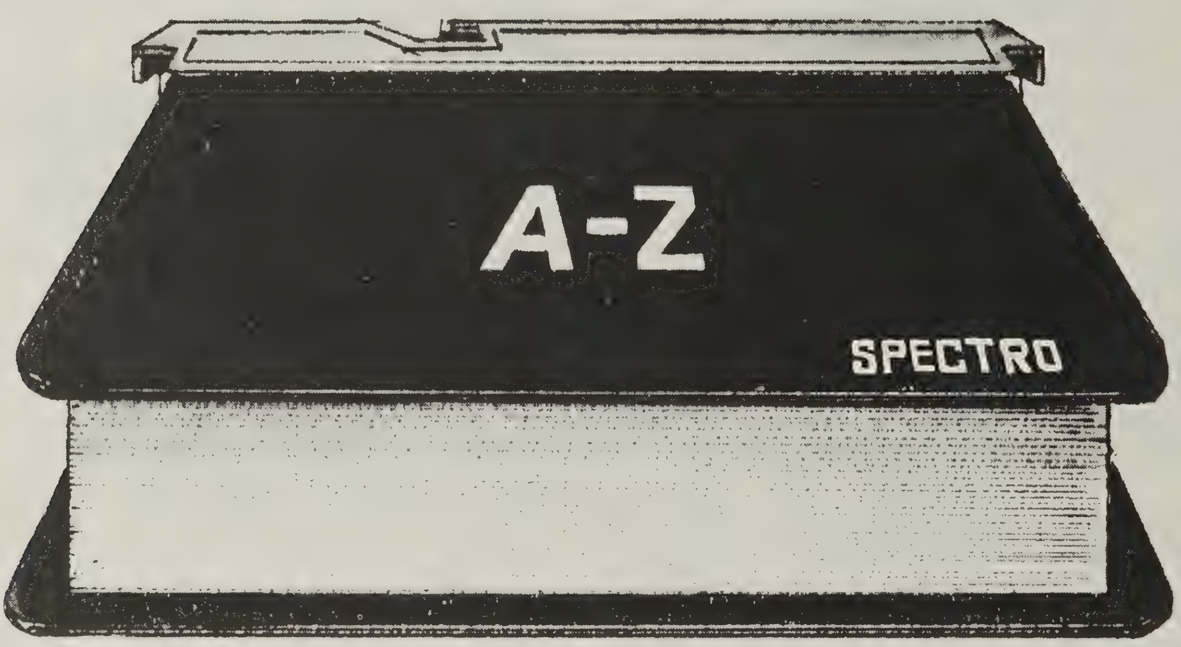

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Keep this Page

The Maryland Drug Product Selection Law Reprinted for your use

Recently the Board of Pharmacy expressed concern that some Maryland Pharmacists might not be familiar with the provisions in State Law for drug product selection. We are reprinting the law here for the use and reference of Maryland Pharmacists. It is important to remember that drugs interchanged under this law must be listed in the Maryland Formulary. Even if a generic drug becomes available on the market and appears in the FDA's list of therapeutic equivalants, it *must* appear on the State's Formulary before drug product selection under this Act can take place.

§ 12-508. Substitution of generic equivalent for brand name drug products.

(a) *Definitions.*—(1) In this section, the following words have the meanings indicated.

(2) *"Brand name"* means the proprietary name a manufacturer places on a drug product or its container.

(3) *"Commissioner of Food and Drugs"* means the Commissioner of Food and Drugs of the United States Food and Drug Administration.

(b) *In general.*—A pharmacist may substitute a generically equivalent drug product, of the same dosage form and strength, for any brand name drug product prescribed, if:

(1) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed;

(2) The substitution is recognized in the formulary of authorized substitutions published by the Department under subsection (d) of this section; and

(3) The consumer is charged less for the substituted drug than the price of the brand name drug.

(c) *Requirements of substitution.*—If a drug product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that the drug product dispensed is a generic equivalent of the prescribed drug product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug product.

(d) *Formulary of authorized substitutions.*—The Department shall publish and, at least every 6 months, update a formulary that lists those substitutions that may be made under this section. The formulary:

(1) Automatically shall list all drug products that the Commissioner of Food and Drugs has:

(i) Approved as safe and effective; and

(ii) Determined to be therapeutically equivalent;

(2) Automatically shall list all drug products that:

(i) Were not subject to premarketing approval for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act;

(ii) Are manufactured by firms meeting the requirements of that act;

(iii) Are subject to pharmacopoeial standards that are adequate to assure product quality; and

(iv) Have been determined by the Commissioner of Food and Drugs to meet any other requirements necessary to assure therapeutic equivalence; and

(3) May list any additional drug products that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic equivalence.

(e) *Distribution of formulary.*—The Department shall distribute the formulary and its revisions to:

(1) All of the pharmacies in this State;

(2) All authorized prescribers in this State; and

(3) Any other person whom it considers appropriate.

(f) *Public education; monitoring of implementation.*—The Department shall:

(1) Assess the need for public education regarding the provisions of this section;

(2) Provide whatever public education regarding the provisions of this section that it considers appropriate; and

(3) Monitor periodically the effects of this section.

(g) *Effect on liability.*—A pharmacist who substitutes a drug product in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug product than would be incurred in filling the prescription by dispensing the prescribed brand name drug. (An. Code 1957, art. 43, § 273A; 1981, ch. 8, § 2; 1982, ch. 335.)

GRASS ROOTS 21

PROGRAM FORMAT

(see President's Message)

FRIDAY, MAY 2

7–9 PM	After Dinner Reception

SATURDAY, MAY 3

8–8:30 AM	Continental Breakfast
8:30–9 AM	Greetings Keynote—Larry Braden
9–10:15 AM	Workshops, concurrent sessions* I. Changing Needs and Goals in Pharmacy Education II. Economics vs. Ethics of Health Care III. Will Medical Supermarkets Doom the Independent? IV. New and Non-Traditional Pharmacy Roles (or What Profession or Business Are We In?)
10:15	Break
10:30–12:00	Workshops, concurrent sessions
12–1 PM	Lunch
1–2:15	Workshops, concurrent sessions
2:15	Break
2:30–4	Workshops, concurrent sessions
4–5 PM	Plenary Session Doug Hepler, Wrap Up, Summary Proceedings to be distributed

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* Sections will rotate through 4 workshops. Leaders and Reporters will remain same.

Continuing education credits will be offered.

Lilly Digest Results for Mid Atlantic Region

FOR: DELAWARE, D.C., *MARYLAND*, SOUTH CAROLINA, WEST VIRGINIA

AVERAGES PER PHARMACY	1984 *SOUTH ATLANTIC STATES* (184 Pharmacies)	1983 *SOUTH ATLANTIC STATES* (215 Pharmacies)	1984 AVERAGES *UNITED STATES* (1,341 Pharmacies)
SALES			
Prescription	$ 337,175— 66.0%	61.2%	60.5%
Other	173,618— 34.0%	38.8%	39.5%
Total Sales	$ 510,793—100.0%	$ 524,552—100.0%	$ 571,313—100.0%
COST OF GOODS SOLD	339,313— 66.4%	66.1%	67.0%
GROSS MARGIN	$ 171,480— 33.6%	33.9%	33.0%
EXPENSES			
Proprietor's or Manager's Salary	$ 33,374— 6.5%	6.4%	5.8%
Employees' Wages	52,986— 10.4%	11.2%	10.5%
Rent	10,738— 2.1%	2.2%	2.4%
Miscellaneous Operating Expenses	54,726— 10.7%	10.6%	11.2%
Total Expenses	$ 151,824— 29.7%	30.4%	29.9%
NET PROFIT (before taxes)	$ 19,656— 3.9%	3.5%	3.1%
TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit)	$ 53,030— 10.4%	9.9%	8.9%
VALUE OF INVENTORY AT COST AND AS A PERCENT OF SALES			
Prescription	$ 35,781— 10.6%	10.5%	10.5%
Other	37,736— 21.7%	20.5%	21.7%
Total Inventory	$ 73,517— 14.4%	$ 75,484— 14.4%	$ 85,458— 15.0%
ANNUAL RATE OF TURNOVER OF INVENTORY	4.8 times	4.8 times	4.6 times
NUMBER OF PRESCRIPTIONS DISPENSED			
New	13,796— 47.8%	47.5%	48.6%
Renewed	15,051— 52.2%	52.5%	51.4%
Total Prescriptions	28,847—100.0%	31,355—100.0%	28,776—100.0%
PRESCRIPTION CHARGE	$11.69	$10.24	$12.00
NUMBER OF HOURS PER WEEK			
Pharmacy was open	61 hours	63 hours	62 hours
Worked by proprietor	47 hours	47 hours	48 hours
Worked by employed pharmacist(s)	34 hours	40 hours	38 hours

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* Source: 1985 *Lilly Digest*

TAXES

By Jo Ann Zito, CPA,
Comprehensive Accounting Services, Towson, Md.

The profitable sale of property used in your trade or business or of property held for investment results in tax being imposed upon the profit even though you intend to purchase a similar replacement asset. The amount of the tax partially depends upon whether the sale results in long-term capital gain or ordinary income. The tax on ordinary income could be approximately 60 percent greater than the tax on a capital gain.

If you are considering selling property in your trade or business, or property held for investment so that you can use the proceeds to obtain similar property for your business, you should consider making an exchange of property. No gain or loss is recognized upon the exchange of property held for the productive use in a trade or business or investment solely for property of the like-kind to be held either for productive use in business or for investment. This non-recognition of gain upon an exchange does not apply for exchanges of inventory, sale of stocks, bonds, notes or various other intangible assets.

Exchanges involving real estate are frequently used where owners desire to sell a piece of real estate and purchase another parcel. Exchanges can also be used for tangible property such as automobiles or equipment used in your trade or business. For example, assume that you desire to trade in your automobile but instead of trading your auto for a new car you decide that you can receive more for the car by selling it yourself than by trading it to the dealer. Any gain that is realized on the sale of your automobile will be subject to income tax even though you immediately reinvest the proceeds in the purchase of a new automobile.

In order for the gain on an exchange of property to be non-taxable, it must be a like-kind. An exchange of real property for personal property is not a like-kind exchange. However, the exchange of vacant real estate for improved real estate such as apartment building or commercial property is a like-kind exchange.

The gain on the exchange is merely deferred since your cost basis of the new property will be reduced by the amount of gain that is unrecognized. As a result of today's high rate of inflation, substantial economic gain can be achieved by deferring the payment of income taxes that would otherwise be due if you sold the property for cash instead of making a like-kind exchange.

Convention Awards

The Awards Committee of the Maryland Pharmaceutical Association is soliciting nominations from the membership for two prestigious awards which are presented to pharmacists at the Annual Banquet. The Committee decided that more membership input into the Awards process would be appropriate. The two Awards are:

BOWL OF HYGEIA This award is presented annually through the cooperation of the A. H. Robins Co. to a pharmacist who has compiled an impressive record in the area of community service.

MPhA ACHIEVEMENT AWARD This recently instituted award is given to a pharmacist who is distinguished in the area of contributions to the profession of Pharmacy.

Nominations for either of these two awards may be sent to the Awards Committee for consideration. Nominations must be in writing and should outline the qualifications of the individual for the award being considered. Nominations are kept on file each year and may be considered by the Awards Committee in future years. Nominations or inquiries about the nominating process should be sent to the M.Ph.A., 650 W. Lombard Street, Baltimore, Maryland 21201.

Convention Resolutions

The Vice Speaker of the House of Delegates, Elwin Alpern, also serves as Chairman of the Association's Resolutions Committee. The Committee will be meeting soon to consider issues and resolutions for the Annual Convention of the Association, June 22–26, 1986 in Ocean City, Maryland. In order to allow for greater membership participation in the resolution process which forms the basic policy making structure of the Association, the Committee is soliciting input from the membership in the form of suggested resolutions or resolution topics. Resolutions may be sent to the Association at this time with any background or supporting information necessary. They should be sent to the M.Ph.A. Resolutions committee, 650 West Lombard St., Baltimore, Md. 21201.

The Industry Relations Committee Says:

Make February The Month You Clean Out Dated Merchandise

The Industry Relations Committee of the Maryland Pharmaceutical Association formed a subcommittee to study the issue of a Model Return Goods Policy. It was the feeling of the Committee, which is made up of manufacturing representatives and practicing pharmacists, that the policy should be fairly comprehensive and yet, provide some guidance and consistency in this area. The goal of the Committee was to develop a policy which could be endorsed by the Association in an attempt to establish a standard and which would be acceptable to both manufacturers and retailers.

The Committee recommends that members retain this page from the journal and refer to the following MPhA adopted policy whenever a question concerning returning merchandise arises. In addition, the Industry Relations Committee serves as an ombudsman whenever members refer a problem concerning this subject in writing to it.

MODEL RETURN GOODS POLICY

1. **New prescription drug products shipped to the pharmacy automatically by the manufacturer or wholesaler may be returned at any time for credit or exchange.**
2. **Regardless of expiration dates products may be returned for credit or exchange at any time, providing they are sealed, intact, original packages.**
3. **For patient protection, open packages of prescription drug products which are outdated may be returned for at least partial credit.**
4. **Authority for returns may be required by the pharmaceutical manufacturer or wholesaler—a form should be provided to the pharmacy.**

SAMPLE FORM to Return Merchandise

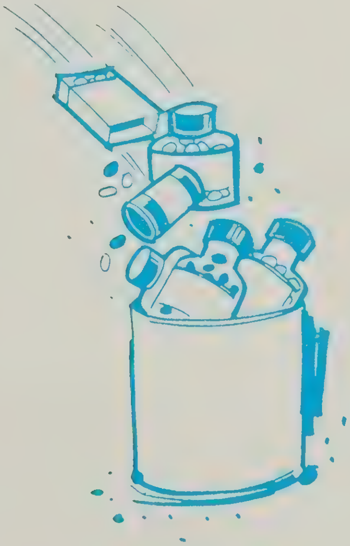
TO: (Name of Manufacturer)
Address — including the name of Town, County,
State and Zip Code

(Note — the above as well as the policy for making returns may be located in the NWDA list of Mfgs. in January 1977 edition of the American Druggist Blue Book).

Please grant us authorization to return the following pharmaceuticals of your manufacture as per your policy:

It is best to list the items — listing complete packages as well as open containers. If a return of a schedule 2 is requested, be sure to give exact count and hold these aside as they usually will send a narcotic form. (Because of mail rates, it may be less expensive to have the drug inspectors destroy them.)

Note — If in their reply, they say they do not accept open containers — or — partially filled ones, call their attention to the fact that for the protection of the patient, as well as the pharmacist and the manufacturer, you believe it best they change their policy to permit them to accept them for credit.



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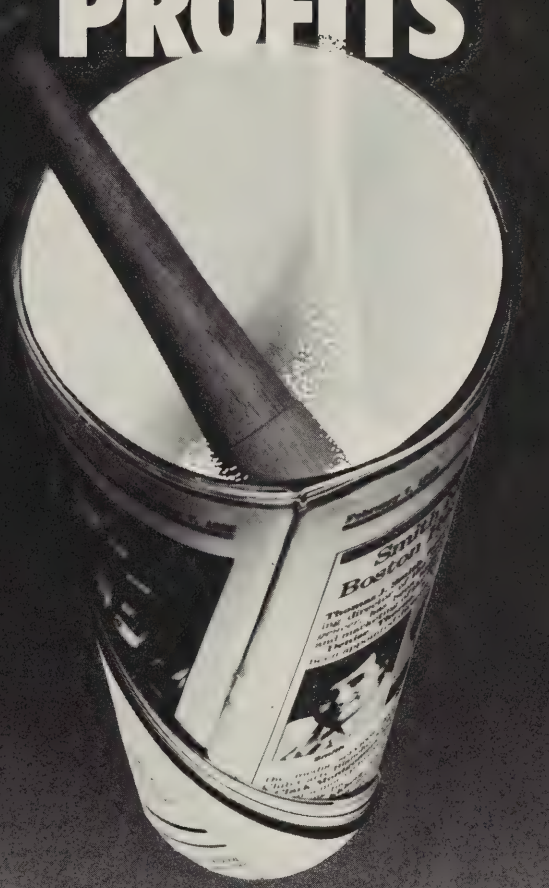

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Thanks to MPhA Lobby Fund Contributors

The following pharmacists have contributed to the MPhA Lobby Fund as of press time. The Association has retained Mr. Judson Garrett as a professional legislative representative to assist in the 1986 Lobby effort. The three main issues which the Legislative Committee have identified for action are: regulation of Dispensing Physicians, regulation of mail order prescriptions, and immunity for the Rehabilitation Committee. These issues affect every Maryland Pharmacist! *It's Not Too Late* to join this list. The Lobby Fund Raising effort does not stop now. We will continue to publish the names of those concerned pharmacists who contribute to this special fund raising effort. Send in your check to the MPhA office for $20.00 or more. Lobbying for Pharmacists is expensive. Help us Hang in There for you.

Hang in There

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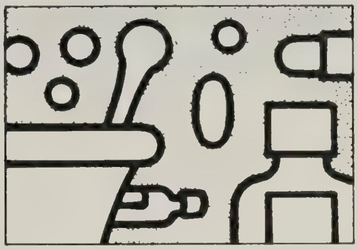
To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

Things You Should Know FOR YOUR GOOD HEALTH



Things You Should Know About Prescription Drugs

You see your doctor, get a prescription, have it filled by your pharmacist, and take the medication. Isn't that all you need to know about prescription drugs?

No!

Drugs are powerful chemicals. Along with their benefits, they also have a potential for harm. Some drugs can cause side effects (adverse reactions). Usually these are mild — a slight rash, mild headache, nausea or drowsiness; sometimes they are severe — prolonged vomiting, bleeding, marked weakness or impaired vision or hearing.

These are warning signals that the medication is causing problems. When a reaction is unexpected or severe, consult your doctor immediately. Not everyone reacts the same way to medication. One person may experience a reaction to a certain drug, while another person may have no problems at all.

Two or more drugs taken at the same time can interact and affect the way one or the other behaves in the body. For example, an antacid will cause a blood-thinning (anticoagulant) drug to be absorbed too slowly, while aspirin greatly increases the blood-thinning effect of such drugs.

Two drugs with the same effect when taken together can sometimes have an impact greater than would be expected. This is called potentiation. Potentiation can be helpful, as when the antibiotic trimethoprim is used to boost the effect of another antibiotic, sulfamethoxazole in combatting certain infections. Potentiation also can be dangerous, particularly when several central nervous system depressing drugs are involved. Even non-prescription medications, such as antihistamines that are often used to fight colds, can increase the sedative effects of anesthetics, barbiturates, tranquilizers and some pain-killers.

Because of these side effects and drug interactions, it is important that you tell your pharmacist if you:

- Have had allergic reactions to drugs or foods, such as rashes or headaches.
- Are taking any medications on a regular basis, such as contraceptives, insulin, antihypertensives, or if you use any non-prescription drugs on a routine basis, such as aspirin or antacids.
- Are being treated for a different condition by another physician.
- Are pregnant or breast-feeding.
- Have diabetes, kidney or liver disease.
- Are on a special diet or are taking vitamin and mineral supplements.
- Use alcohol or tobacco.

What's on your prescription?

The first word on the prescription is the name of the drug. Next is the dosage form (liquid, capsule, tablet) and the strength. Next is the amount you will get followed by the directions for use. These are often abbreviations of Latin words. The pharmacist will translate this information onto the label of the medication container.

It's a good idea to check the medication container before you leave the pharmacy. If there is anything you don't understand, ask your pharmacist.

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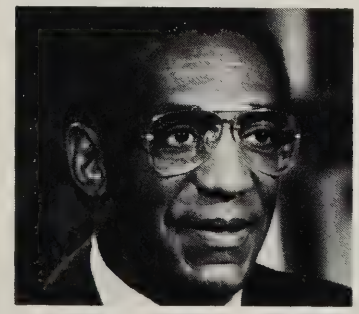
Bill Cosby says: "When you learn CPR, you're ready to save lives– anywhere."



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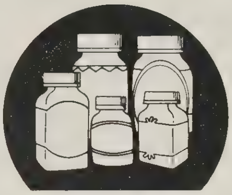
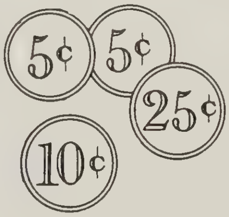


Nine of this country's ten top-selling drugs now face competition from generic versions—a situation which the U.S. Department of Health and Human Services estimates can save American consumers between $500 million and $1 billion a year. According to HHS Secretary Margaret M. Heckler, "Drug purchasers who want to save dollars should ask doctors—ask pharmacists—'Is there a generic equivalent I can get at a lower cost?'" Generic versions have been approved or are already available for these top sellers: hydrochlorothiazide-triamterene, propranolol HCl, digoxin, diazepam, acetaminophen-codeine, amoxicillin, furosemide, ibuprofen, and acetaminophen/prophoxyphene napsylate. The only drug among the top ten still enjoying patent protection is cimetidine, which received FDA approval in 1983.

Cost Shifting Subsidy



Inadequate reimbursement rates of third party prescription programs are causing private-paying customers in the community pharmacies of at least one state to pay a "significant" cost-shifting subsidy amounting, on average, to 52¢ per prescription. That was the finding of a pilot study on third party induced cost shifting in Indiana pharmacies, revealed by Jon Stone, PhD, at an APhA seminar. Stone, now on the APhA staff, defined cost shifting as "the practice of charging more to one group of customers because another group of customers is not paying the full price for a particular product or service." The study found that the greatest proportion of cost shifting in the state was caused by the inadequate reimbursement rates of Indiana Medicaid.

Young Less Compliant

Younger people, men, college graduates, and those in upper income brackets are least likely to follow their physician's instructions about the correct use of prescription drugs. So say the findings of a Louis Harris and Associates survey, titled "Americans and Their Doctors," commissioned by Pfizer Pharmaceuticals. Age proved to be the most significant indicator of compliance. Nearly half (48%) of those aged 18-24 admitted to not following the physician's instructions all the time, but by the time one looks at the age range 65-74, a full 81% report they always comply with the instructions The most common forms of noncompliance were taking a little less of a drug, or taking it less frequently than directed. Reasons for noncompliance included: feeling better (noted as a reason by 72% of those surveyed), just forgetting (63%), concern about negative side effects (46%), concern about possible interactions with other drugs (31%), uncertainty about effectiveness of medicine (38%), and cost of the medicine (22%).

Diversion Schemes

Discriminatory pricing is a critical link in some of the diversion schemes recently revealed by the FBI and the U.S. House of Representatives Subcommittee on Oversight and Investigations. Key to these schemes, says the subcommittee's report, are "nonprofit institutions [that] have purchased pharmaceuticals beyond their needs and diverted the excess to the wholesale market for many years." What's new, the report says, is that the "volume of merchandise and the number of diversions from nonprofit institutions appear to have increased dramatically." The evidence amassed to date demonstrates that the opportunities for successful and profitable drug diversion schemes are enhanced by the widely varying prices for pharmaceuticals at the manufacturer and wholesale levels of drug product distribution.

Provided as a service by the American Pharmaceutical Association.

From the M.Ph.A. Legislative Committee: Heres what you can do to help

REGISTRATION AND VOTING

1. Register to vote and encourage family and friends to register also.
2. Check out absentee registration rules with your local registrar if you are out of town frequently.
3. Vote in primary and general elections and encourage family and friends to vote also.
4. Vote by absentee ballot if you are going to be out of town.

PARTY AND CAMPAIGN ORGANIZATION

1. Get active in a political party of your choice.
2. Serve on a political party committee.
3. Work on a candidate's campaign committee.
4. Volunteer to:
   a. help a candidate or party address and stuff envelopes
   b. distribute campaign liturature in your neighborhood
   c. prepare voter index cards and lists for campaigns
   d. work in a phone bank to recruit other party workers or get people out to vote on Election Day
   e. organize rallies and fund-raising events
   f. type letters
   g. act as a poll watcher
   h. host a coffee/tea party for a candidate
   i. design campaign posters and ads
   j. give rides to the polls
   k. be a precinct worker or a block captain
   l. write campaign material
   m. babysit for voters with small children on Election Day
   o. decorate meeting halls
   p. help publicize campaign and party events through the media

FUNDRAISING

1. Contribute financially to a political party or candidate and solicit funds from others.
2. Volunteer your services to provide expertise in election laws, accounting, fund-raising, marketing and promotion.

SUBSTANTIVE ACTIVITIES

1. Keep informed on vital issues facing the community and government.
2. Know the candidates and their qualifications.
3. Attend meetings of the city council, school board, or other public boards.
4. Communicate on issues with your elected representatives — local, state and national.
5. Write letters to the editor stating your position on a particular issue.
6. Hold appointive or elective office in government.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the
St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor
and Leonard L. Naeger, Ph.D., Associate Editor

VANCOMYCIN:

Vancomycin is a drug which is both ototoxic and nephrotoxic. It is useful in several situations where other drugs fail, but its plasma levels need to be monitored in order to prevent toxicity. This is especially true in elderly patients. *Clin Pharmacol Ther,* Vol. 36, #6, p. 803, 1984.

LITHIUM:

Lithium salts produce effects on a variety of physiological systems including enkephalin synthesis and adenyl cyclase activity. Dopamine and norepinephrine turnover rates are slowed in depressed patients treated with lithium salts, but these changes are not seen in normal volunteers given the drug. The reason for the differential effect seen in patients with manic-depression is not known. *Clin Pharmacol Ther,* Vol. 37, #1, p. 66, 1985.

TOMOXETINE:

A new antidepressant has been tested and found to have a potent effect in depressed patients. The drug, tomoxetine, is a selective inhibitor of norepinephrine uptake but does not affect either serotonin or dopamine activity as is the case with the majority of antidepressant agents currently available to the medical community. Tomoxetine is said to produce fewer anticholinergic side-effects than agents used for similar purposes. *J Pharmacol Exp Ther,* Vol. 232, #1, p. 139, 1985.

AMIFLOXACIN:

A new antibiotic, amifloxacin, was compared in vitro to several currently used antibiotic agents including ticarcillin (Ticar), moxalactam (Moxam), azlocillin (Azlin), cinoxacin, trimethoprim, and amikacin (Amikin). The newer agent was found to be more effective than any of the others as measured by this in vitro method. Pathogens studied included Pseudomonas aeruginosa, Aerobacter, proteus and A. calcoaceticus. Other similar derivatives being examined include nonfloxacin, enoxacin, and ceprofloxacin. Amifloxacin is being investigated by Sterling-Winthrop Research Institute in New York. *Clin Ther,* Vol. 7, #1, p. 73, 1985.

VOLATILE SUBSTANCES:

Deaths due to inhalation of volatile liquids are occurring in increasing numbers in Great Britain. The majority of the deaths are associated with solvent abuse which leads to cardiac abnormalities. Cleansing agents accounted for 31% of the fatalities while butane was involved in 24% of the deaths. Aerosol sprays and solvents in glue accounted for 34% of the mortality figures. Most deaths occurred in males between the ages of 15 and 20 years. Since few deaths occurred in children under the age of 14 years, limiting the distribution of glues in this age bracket would not have a dramatic effect in reducing death via inhalation. A significant number of deaths were also attributed to asphyxiation. *Br Med J,* Vol. 290, #6464, p. 304, 1985.

PONTIAC FEVER:

Pontiac fever, unrelated to strong inclinations toward a type of automobile, has been characterized as an acute, self-limiting condition which is exemplified by symptoms which include chills, fever, chest pain, cough and nausea. An outbreak of this condition has been traced to the organism Legionella pneumophilia, Serogroup 6. The infection is thought to be spread during this outbreak through vapors created by the aerator of a heated whirlpool bath. *JAMA,* Vol. 253, #4, p. 535, 1985.

MEPERIDINE:

Meperidine (Demerol) is said to be more effective in elderly patients than in younger adults. Studies conducted in healthy patients between the ages of 60 and 79 years indicate that any potentiation of meperidine activity or toxicity is due to factors other than those related to age-induced alterations in disposition of the drug. Increased central nervous system sensitivity may be responsible. *Clin Pharmacol Ther,* Vol. 37, #1, p. 19, 1985.

PIROXICAM:

The non-steroidal anti-inflammatory drugs (NSAIDs) are used extensively to control pain and inflammation associated with various conditions, including arthritis. The effects of piroxicam (Feldene) are long lasting and its half-life is such that the drug can be administered in single daily doses. This is often felt to be a way of increasing compliance, especially in the elderly arthritic patient. Investigators have found that the drug tends to accumulate because of its 48 hour half-life. The effect is most dramatic in elderly females and because of this reduced drug clearance, patients receiving it should be monitored closely and dosage reductions made where appropriate. *Clin Pharmacol Ther,* Vol. 37, #1, p. 13, 1985.

ASTHMA:

Patients with severe acute asthmatic conditions were examined when they were admitted to an emergency care facility. The plasma levels of circulating catecholamines were determined and were found to be much lower than would be expected during an adrenergic or emergency type of situation. Since levels of these catecholamines are elevated during myocardial infarctions, heart failure, and septicemia, investigators feel that asthmatics lack the ability to secrete catecholamines during this respiratory emergency and thus the severity of the attack is increased. *Br Med J,* Vol. 290, #6363, p. 267, 1985.

DEMENTIA:

It is sometimes difficult to evaluate the decline in mental capacity of older persons although such an evaluation could help determine which patients are deteriorating at a faster rate than would be expected if based on age considerations alone. Scientists at the University of Iowa have compared the results of three neuropsychological examinations in patients aged 60 through 88 years and have concluded that this battery of tests can be used effectively to determine if an elderly patient is deteriorating mentally at a rate greater than should be expected. This would identify that patient and allow for special considerations in their treatment. *JAMA,* Vol. 253, #5, p. 671, 1985.

WILSON'S DISEASE: Hepatolenticular degeneration or Wilson's disease is a genetic defect which allows for deposition of copper in the liver, brain, kidney and cornea. It is generally fatal if untreated. Therapy with penicillamine (Cuprimine) is useful in that it complexes the copper ion and promotes its excretion. However, penicillamine is not without serious side effects and some patients cannot tolerate its administration. Two patients not able to tolerate penicillamine were given zinc sulfate three times daily. The zinc apparently inhibits the uptake of copper from the gastrointestinal tract and reduced the progression of the disease. After two years of therapy the copper concentration in the body, as measured by intravenous radiocopper loading test and liver biopsy, showed a reduction in the total concentration of body copper. *Br Med J,* Vol. 289, #6440, p. 273, 1984.

FEMALE ATHLETES: Amenorrhea in the highly trained female athlete has been associated with a reduction in estrogen concentration. Since reduced estrogen levels in post-menopausal women is associated with demineralization of bone, it was necessary to examine these athletes to determine if low estrogen levels induced by strenuous exercise might also contribute to reduced bone density. Results of a study utilizing matched groups of female athletes indicate amenorrheic athletes do demonstrate signs of reduced bone density. *N Engl J Med,* Vol. 311, #5, p. 277, 1984.

PROTEIN BINDING: Albumin will bind drugs at three distinct binding sites. Site I binds diazepam (Valium), Site II binds digitoxin, and Site III binds warfarin (Coumadin). Since the concentration of albumin is reduced toward the end of pregnancy, it was of interest to determine what effect this reduction in plasma protein might have on drug activity. During the latter stages of pregnancy, the reduction in albumin concentration was associated with a reduced binding of drugs at Site I and Site II, but a concomitant increase in affinity for drug binding was noted at Site III. *Clin Pharmacol Ther,* Vol. 36, #2, p. 201, 1984.

STEROIDS AND BODY BUILDING: For years, controversy has clouded the issue of anabolic steroid use in body building. No reproducible studies have surfaced which indicate a clear advantage in the use of these drugs in the developing athlete. The recent Olympic games has revived interest in this topic. Anabolic hormones do seem to increase plasma lipids, and thus may increase the risk of coronary heart disease. Additionally, muscle tissue formed while under the influence of these steroids has been found to contain anatomical abnormalities. While controversy still surrounds the use of these steroids in athletes, a growing group of clinicians feel steroids should not be used as an adjunct for body building. *JAMA,* Vol. 252, #4, p. 507, 1984 and *Am Fam Physician,* Vol. 30, #1, p. 113, 1984.

RANITIDINE: Patients were randomized for treatment with ranitidine (Zantac) in doses of either 150 mg twice daily or 300 mg taken as a single night-time dose. Over 100 patients participated in the study which produced data which suggest that the single dose regimen was as effective as the more conventional one. An increase in patient compliance may be an advantage of the single dose regimen. *Lancet,* Vol. II, #8397, p. 274, 1984.

CHRONIC ABDOMINAL PAIN: Patients who have abused narcotic agents may develop severe constipation and mechanical bowel obstruction. Clinicians have found that the administration of clonidine (Catapres) may help alleviate this problem. They suggest that narcotic bowel syndrome be considered when chronic abdominal discomfort is the chief complaint. Clonidine has been found useful in preventing or amilorating the effects of narcotic withdrawal in general. *Ann Intern Med,* Vol. 101, #3, p. 331, 1984.

WARFARIN: Approximately 260 patients participated in an anticoagulant clinic which involved the administration of warfarin (Coumadin). Patients returned for re-evaluation every month. It was estimated that approximately 50% of the participants were not sufficiently anticoagulated. A system was devised by which the information obtained from the blood tests was fed into a computer along with other pertinent information. Clinicians found the computer did as well as manual readjustments, but increased the efficiency of both medical and secretarial time. *Br Med J,* Vol. 289, #6442, p. 422, 1984.

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DIABETES CE PROGRAM—A NEW APPROACH

The CECC diabetes program "Diabetes" to be presented in May, 1986, will have a unique format that will enable material presented to be readily adapted into pharmacy practice. CE generally provides the information pharmacists should know in order to practice. However, limited time is available to teach them how to integrate knowledge into practice. The May participants will receive the factual information in advance. The program itself will then concentrate on using this knowledge in practice. Small group and/or workshop formats will be utilized where possible to facilitate student/instructor interactions. Detailed information regarding this program will be forthcoming shortly.

For information contact:

Marvin L. Oed
528-7118

RX LICENSE PLATES

Again this year, the MPhA will be making available a special line of license plates from the Department of Motor Vehicles for Pharmacist members of MPhA. A special one time fee of $10.00 per vehicle will be required and should be added to the fees specified by DMV. Mail the total check and forms to MPhA for processing. The tags will have the "RXA" prefix and numbers will be given on a first come—first serve basis. Watch for further details.

calendar

Feb. 2, Sun.—MPhA Mid Year Meeting, Annapolis-Hilton
Feb. 13, Thurs.—MSHP Monthly meeting
Feb. 20–27—MPhA Trip to PUERTO VALLARTA, MEXICO
Mar. 6–9—NARD Home Health Care Conference —Baltimore
Mar. 9, Sun.—BMPA Dinner Dance—Bluecrest North
Mar. 13, Thurs.—MSHP Monthly meeting
Mar. 15–20—APhA Convention, San Francisco
Mar. 16–22—National Poison Prevention Week
April 6, Sun.—Fritz Berman AZO Seminar
April 20, Sun.—CECC C.E. Seminar on "Family Planning"
May 2–3—Grass Roots—21, MPhA, VPhA Conference
May 18, Sun.—CECC "Diabetes" C.E. Seminar
June 20–22—MSHP Seminar, Ocean City, Contact Paul Jeffreys 528-5650
June 22–26—MPhA CONVENTION SHERATON HOTEL, OCEAL CITY . . . THINK WARM

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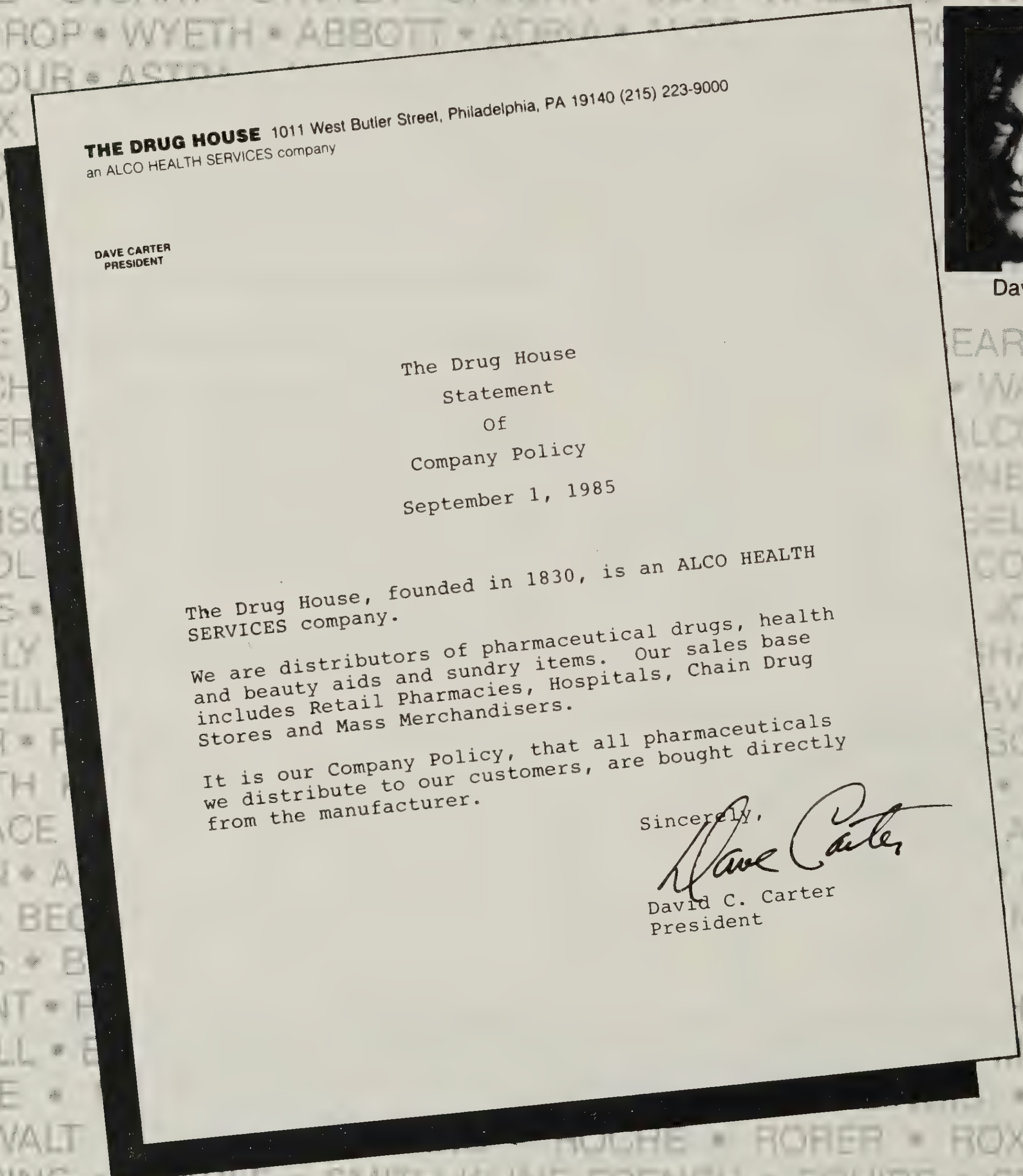

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DAVE CARTER
PRESIDENT

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Statement
Of
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September 1, 1985

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We are distributors of pharmaceutical drugs, health and beauty aids and sundry items. Our sales base includes Retail Pharmacies, Hospitals, Chain Drug Stores and Mass Merchandisers.

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Sincerely,

Dave Carter

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Elder-Health Partnership in Care

by Peter P. Lamy, Ph.D., F.A.G.S.
Madeline Feinberg, Pharmacist.

developed by: University of Maryland School of Pharmacy
William J. Kinnard, Jr., Ph.D., Dean

ELDER-HEALTH

A program in two parts, aimed at health maintenance/recovery for older adults

Program Part	*Target Audience*
Elder-Ed Program	The Elderly (seniors)
Caregiver Program	Family (direct caregivers) Significant others Health care professionals

ELDER-ED

A pharmacy-based drug education program for senior adults

SUPPORTED BY: THE PARKE-DAVIS COMPANY
Div. Warner Lambert Co.
Morris Plains, New Jersey

and

The Maryland Pharmaceutical Association
A Centennial project 1982

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
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TELEPHONE 301/727-0746

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President's Message

The Elder-Ed Program is moving into its eighth year and has greatly expanded activities since its inception. Nearly 200 pharmacy students have enrolled in the program and have presented over 1000 talks in their communities to elderly about medications. In 1982 the Maryland Pharmaceutical Association adopted the program as its Centennial Project and pharmacists statewide—Clint Englander in Oakland, Larry Hogue in Westminster, Lane Zangwill in Prince Frederick, Arnold Paige in Cambridge, Dave Russo in Hagerstown, Dave Leiberman in Baltimore, Gene Borowski in Gaithersburg, to name a very few—have used the Elder-Ed program as the model for their community outreach efforts. Hospital pharmacists use this program to present to patient groups. Long term care practitioners use this program with adaption to inservice nursing personnel. In 1983, the enlarged Elder-Health Program received the Margaret M. Heckler Secretary's Award for Excellence for Community Health Promotion, the only pharmacy program to receive such an award.

Also, in 1983 the Parke-Davis Company gave a major grant to the University of Maryland School of Pharmacy to support the Elder-ED Program, its faculty and research. In addition, Parke-Davis developed its own Elder Care Program which brings the Elder-Health concepts to pharmacy organizations across the country. Through the Parke-Davis Center for the Education of the Elderly established at the U. MD. School of Pharmacy, an international award-winning video, *The Medicated Generation*, has been produced and seen nationwide on public television. A quarterly newsletter abstracting the literature on medications, nutrition, oral health and patient education is distribute5d to more than 20,000 providers who care for elderly. Pamphlets on taking medications, generic drugs, OTC's, vitamins, nitroglycerin, chosing a pharmacist, taking care of skin and eyes, a caregiver's medication guide, and a patient medication record card have been produced and sent to more than one half million patients and providers here and abroad. Several have been reprinted into spanish and french.

Dr. Peter Lamy, this Association's 1985 Honorary President, developed the Elder-Health Program and is recognized for his boundless energy as a spokesman for the elderly and a spokesman for pharmacy. He always reminds us: the elderly are here to stay and in greater numbers:

—that 95% of elderly remain in the community, not in nursing homes
—that 80% of elderly have children, most of whom live within short distances
—that the very old are the fastest growing segment of the population and are most likely to suffer multiple impairments and chronic disease
—that therapeutic management will include *more* than meeting simple medical needs; rather we will look to multiple providers within the community to coordinate activities to maintain elderly independence
—that health promotion and disease prevention will be emphasized to prevent or delay onset of chronic disease,
—that pharmacists are still the most accessible health care resource in the community.

He is right! We are still the medication experts. We still care for the vast majority of elderly patients. We still see their family members regularly. We can serve as part of the community-based health care team. But in today's cost-conscious climate, there is fierce competition for the patient. *We must be seen or be forgotten!* The Elder-Health Program and the Maryland Pharmaceutical Associately jointly offer support to the pharmacists of this state. Use our programs and materials. Maintain your visibility!

Starting with this issue, the *Maryland Pharmacist* will publish updated speaker outlines of the most popular Elder-Ed community presentations. Also, beginning with the April issue, the Parke-Davis Center for the Education of the Elderly will publish a column "Timely Tips" which will explore in depth issues of concern for those who manage elderly. The initial columns will feature osteoporosis, its pathophysiology, epidemiology, prevention and management. I look forward to your comments.

Madeline Feinberg,
PRESIDENT

Elder-Health

A Consumer Drug Education Program for Older Adults and Their Caregivers

The primary goal of the Elder-Health program is to assure that patients understand and respond to a particular therapeutic regimen. Additional goals of the program may be stated as follows:

I. General Goals:
  —to assure that the consumer is aware and responsive, one who recognizes that the desired outcome of any health care or specific therapeutic regimen is a shared responsibility between provider(s) and consumer.
  —to offset some of the undesirable effects of mass media advertising regarding drugs and drug products.
  —to recognize (and respond appropriately) to the diminished physical, psychological and economic resources of the elderly, in context with measures and/or medicinal agents recommended.
  —to assist caregivers, those who form the support structure for the elderly, to assertively discuss and negotiate medication issues and problems with the health care provider.

II. Specific Goals:
  —to assure that elderly individuals and their caregivers are knowledgeable regarding their medication regimen.
  —to assure that individuals understand that they need to ask questions of their physicians and pharmacists and what questions need to be asked.
  —to present to older adults facts which argue for the value of preventive care.
  —to increase the consumer's awareness of the value of self-medication, *if performed correctly*.

To this end the Elder-Health program presents a variety of talks and discussions designed specifically for the older audience or their caregivers. Topics selected have been those requested by seniors themselves and are most popular with these groups. The talks reinforce the specific goals stated above while providing general information on medications commonly used by the elderly.

Health care practices, such as self-medication for example, are discussed throughout each talk. Emphasis is continued throughout all discussions regarding the ACTIVE role the health care consumer must pursue and the negative aspects of the passive role of the recipient of care.

It is felt that increasing emphasis must be placed on the caregiver as current trends indicate that more and more older adults will remain in the community and responsibility for their care will increasingly fall on family and neighbors, those who form the community-based support structure. An added bonus: these very caregivers are themselves getting older. By targeting programs to this group, this program aims to create more informed consumers as they move into their senior years.

Something to Think About:

Possible Barriers to Communications with Older Adults

1. It is difficult to talk to older adults about aging and the effects of aging.
2. Older adults want us to listen, hear, care, and respond. They often complain that nobody is "listening". The necessary balance between talking (sending the message) and listening (assuring oneself that the message has been received and understood) is more difficult to achieve with older adults.
3. Older adults may have diminished ability to understand speech and other sounds.
4. The wrong vocabulary will block good communications. Professional and scientific language, used in communicating with any consumer but particularly with older adults, is a major barrier. Scientific or professional language is the equivalent of bad handwriting.
5. It is difficult to overcome social and health behavior that is negatively influenced by social isolation of the consumer.
6. The elderly may adhere to values learned and accepted in their younger years. Younger adults, communicating with them, may have different beliefs and value systems.
7. The provider must overcome the "generally accepted" dictum that you cannot teach older persons anything new, and that a change in health behavior in older age will be of no benefit anymore.

8. The older adult's short-term memory and recall, as well as learning speed (but not learning ability) may be diminished, and, therefore
9. The older adult's attention span can easily be exceeded.
10. Sensory losses or decrements in older adults may be devastating to them and may well prevent good communications:
    a. Auditory loss, of which probably more than one-half of all elderly suffer to different degrees of severity, can be a major barrier to direct communications. Indirectly, auditory loss can lead to very defensive behavior on the part of the consumer and a loss of "trust". Otosclerosis, stroke, mastoiditis, otitis media, nerve damage resulting from the administration of a variety of drugs may have caused or may cause significant auditory decrements in the elderly.
    b. Vision loss: Good sight is essential for identifying medications and taking them correctly according to instructions which are, unfortunately, most often written in small letters on background that interferes with better reception. Probably more than one-half of the elderly suffer from vision impairment, due to such diseases and disabilities as cataracts, glaucoma, dry eye, and others. Primary aging, itself, is most often responsible for lessened acuity.
11. Physical limitations and mobility problems, such as arthritis, may be enormous barriers to good communications and follow-through. For example, serious arthritis and hearing loss may prevent an older consumer, homebound or bed-bound, from communicating effectively by telephone, often the only available means of communication. Arthritis, tremor, and poor eyesight may make it impossible for an older adult to follow directions in administering eye drops.

Once pharmacy practitioners have learned about these potential barriers and have dealt with them appropriately, they need to devise a system or systems to address the large number of elderly which will demand services from them in the near future.

Selected Topics of the Elder-Ed Program

The Wise Use of Medications. Your Rights and Responsibilities as a Consumer

This is a general talk, centered around the Elder-Ed publication *You and Your Medicines*. At this, as well as at all other presentations, the publication *Your Personal Medication Record Card,* is distributed. Filling it out can be a service offered at the pharmacy. It is stressed that the Record Card should be carried by the elder and discussed with every prescriber.

Aging and How it Affects Your Response to Medications

This can be the first in a series of talks which follows the "drug" as it travels through the body. It highlights what changes occur as we get older, and why drugs may act differently in older persons.

Generic Drugs, Prescription Drug Prices, and Pharmacy Services

Saving money and the cost of medications are of major concern to seniors. The pamphlet *Everything You Ever Wanted to Know About Generic Drugs,* can be used along with *How to Choose Your Pharmacy/Pharmacist* in presenting this topic. Advantages and disadvantages of using generic medications, cost savings and therapeutic equivalences (bio-inequivalences) are described. Pharmacy services are also discussed with emphasis on how these services contribute to the health of the patient.

How to Select a Non-Prescription Medication

Guidelines for self-medication are covered with emphasis on the role of the pharmacist in selecting a product with the consumer. Special attention is given to cough and cold preparations, analgesics, laxatives and antacids. Pamphlets entitled *Medicines Without Prescriptions, Skin Care* and *You and Your Eyes* are available for distribution.

Nutrition and Vitamins for the Older Adult

Principles of good nutrition are emphasized. Some of the current vitamin and mineral fads are discussed and caution is advocated for the elderly. The ElderEd pamphlet *Vitamins Are Not Enough* provides the basis for this topic.

an essential point

NEVER UNDERESTIMATE THE DRUG KNOWLEDGE OR DISEASE KNOWLEDGE OF THE ELDERLY!

Format:

Outlines of each topic follow and can be used as a guideline for the speaker. Of course, questions or special audience preference may alter the planned program. Be firm in steering the talk. Set the rules early and request that personal questions be reserved for discussion after the program.

Helpful Hints:

—Present the talk in about 20–30 minutes
—Introduce yourself and the topic. Why was the topic chosen and how will it help the elders?
—Be entertaining! Use anecdotes from your own experience or share a joke if appropriate.
—Slides and posters do not hold attention. Darkening the room distracts from attention and slides

may have too much glare. Posters are hard to read, especially for the elderly who may have vision impairment.
—Speak slowly and clearly, as elderly may have hearing impairment.
—Elderly are interested in themselves and in their personal experiences. Select examples of drugs with which most are familiar, e.g., aspirin, nitroglycerin, hydrochlorothiazide.
—Avoid the term "drug"—use "medication."
—Leave plenty of time after program for questions (even after question period). Be ready to ask questions to break the ice.

Setting Up an Elder-Ed Talk in the Community

Whom to Contact:

—recreation or program directors of local senior groups
—mention to customers
—post signs at prescription counter that pharmacist is available to speak to senior groups
—place ad in local papers
—Area Agencies on Aging
—senior retirement centers

Assuring a Good Turnout:

—give sufficient notice (one month at least) allows people to make plans
—ask director of program to announce in Center newsletter
—request that announcement be made one week prior to talk as reminder

Doing Your Own Publicity

—post notice in pharmacy window (large letters, bright colors)
—ask local merchants to post notice
—ask local radio station to make public service announcement

Sites to Contact: Where We've Been

churches & synagogues
retirement communities
senior citizen housing
public library
local hospitals
social service agencies
Foster Grandparents Program
Senior Companion Program
county commissions on aging
Area Agency on Aging
county and city recreation programs
nursing homes (staff & families)
political groups (e.g. Gray Panthers)
senior organizations (e.g. A.A.R.P.)
eating together sites
senior day care programs

Health Fairs—Some Guidelines for Participation

—insist that pharmacist be responsible for medication screening at registration desk
—give participants their own *Personal Medication Record Card*. You or your students help complete card.
—be sure medication history is taken prior to hypertension screening, glaucoma screening, diabetes screening, others.
—if you identify problem with medication, be certain adequate follow-up service is provided through the Health Fair Site director.

Suggested Group Size: The Audience Size Can Vary from 5 Persons to 500

—get approximate size from director or coordinator so that you have sufficient materials.

Where to Get Pamphlets for Distribution Contact

Elder-Ed Program
School of Pharmacy
University of Maryland at Baltimore
20 North Pine Street
Baltimore, Maryland 21201

You and Your Medicines: Your Rights and Responsibilities as a Consumer

I. Introduction
  1. Introduce self
  2. Involve audience
    —how many people here take at least one medication a day?
    more than one? more than two?
    how many take a vitamin? drink coffee?, alcohol? cigarettes?
II. What is a drug ("medication")?
  1. Define—"simple chemical compound that has a certain therapeutic effect in the body"
  2. What is the therapeutic effect of a medicine (get audience to participate)
    e.g. aspirin: (everyone knows!)
      relief of pain
      reduces fever
      reduces inflammation
      prolongs clotting time (anti-platelet effects)
      reduces risk of death with a previous infarction or unstable angina (be familiar with

latest information especially since elderly have misconceptions about this)

or e.g. propranolol: (many elderly know!)

to prevent chest pain,

to regularize heart beat

to prevent possible fatal arrhythmia following heart attack in certain patients

for high blood pressure

to prevent tremors

to prevent migraine headache

3. But also, *all* medications may have side effects associated with their use:

   e.g. aspirin (get audience to participate)

   stomach irritation, pain

   gastric bleeding

   rash

   anticoagulant (undesirable in some individuals)

   sedating (for some)

   interacts with many medications (anticoagulants, medicines for diabetes)

   or e.g. propranolol

   drowsiness

   loss of energy

   changes in personality

   constipation

   may make certain conditions more difficult to manage, e.g. diabetes, certain heart conditions, asthma

   cannot stop medication abruptly

   may interact with other medications

4. Or if dose is too high, symptoms of toxicity may need careful evaluation by doctor:

   e.g. aspirin

   tinnitus (many elderly may already "hear" ringing or noise in ears)

   e.g. propranolol

   many symptoms of toxicity can easily be confused with "old age"

   Therefore consumers must work together with both doctor and pharmacist to be certain that medication is achieving the desired effect with minimum risk of side effects or excessive dosage.

III. Why are elderly more at risk for the unwanted (or side effects) of medications?

1. They tend to take more medications—risk of drug interactions is greater
2. A drug given for one disease may worsen a preexisting condition ("drug/disease interaction")
3. Elderly may take medication incorrectly: Ask for participation from group
   - —cannot read directions or name of medication
   - —cannot afford medication, so they take it less often
   - —fear of side effects
   - —belief that medicine is not doing any good
   - —forgetful (take multiple medications)

IV. How can you, the consumer, get the most benefit from medications and be exposed to the least risks? Remember. Taking medications is a balance: benefit:risk!

Refer to *You and Your Medicines*

1. When visiting the doctor: suggestions from audience?
   - —what to tell doctor about condition
   - —what to show doctor (medications or Record Card, other doctors)
   - —what to ask doctor about condition, medications prescribed, need to continue current medications
   - —alternative therapy, non-drug treatments?
2. *Personal Medication Record Card*—display, explain how to use
   - —list all prescription medications, including eye drops, topicals
   - —what are medications used for
   - —how to take
   - —have pharmacist complete and keep card up to date
   - —list non-prescription medications (they can affect how Rx works)
   - —advantages of keeping written record and showing to all prescribers

     show to *All* doctors you may visit

     may avoid duplication of medication (e.g. propranolol and Inderal®)

     enables monitoring for drug interactions when reviewed by pharmacist or doctor

V. Chosing a pharmacy . . . Getting prescription filled. Refer to *How to Chose Your Pharmacy/Pharmacist*

1. Selecting a pharmacy. Ask audience what they look for in picking pharmacy
   - —convenience
   - —services? Ask
   - —price
   - —personal attention
   - —other?
2. What you should expect from your pharmacist
   - —directions on how to take medication, e.g. "Three times a day" Meaning?
   - —stress importance of taking with plenty of fluids, *NOT* lying down
   - —non-safety vials (explain how to request)
   - —mixing with other medications?
   - —sharing medications
   - —starting with small quantity then refilling in 100's
   - —mixing with alcohol
   - —storage
   - —when to refill?

VI. Questions from Audience?

Use specific questions to illustrate general points you are making.

If questions are too personal, ask elderly to meet you privately at end of talk!

To end talk, share the following poem. Good finish!

OLD MOTHER HUBBARD

Old Mother Hubbard went to the cupboard
to get her poor stomach a pill.
But when she got there,
she found bottles to spare,
from other times that she'd been ill.

There were capsules, and potions,
and drugs for emotions
prescribed by a dozen physicians.

Some were her brother's
some she'd borrowed from others
who had almost the same conditions.

"I'll throw it all out,"
she said with a shout
"My doctor's advice I will follow.
And take only those pills
prescribed for my ills.
and use my head before I swallow."

LETTERS

Dear Mr. Banta:

The American Society of Hospital Pharmacists has just published a new edition of its *Handbook on Injectable Drugs*. The *Handbook*, now in its 4th edition, is the world's most respected reference on the stability and compatibility of injectable drugs, including investigational drugs. Monographs include concise information on formulation, preparation, dosage and administration, pH and compatibility with base solutions and other additives. All information is fully referenced. The new 4th Edition has been completely revised and updated by the addition of 29 new monographs.

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4630 Montgomery Avenue
Bethesda, MD 20814

I am enclosing a review copy of this new publication. I hope you will bring the *Handbook* 4th Edition to your readers' attention and I would appreciate a copy of any review that you publish.

Sincerely,
James P. Caro, Director
Special Projects Division
Professional Services Development Group

Dear Dave:

The Diabetes Research and Education Foundation, Inc. was formed to provide grants to individuals in all diabetes-related disciplines for projects in diabetes detection, management, and education. Continuing contributions from Hoechst-Roussel Pharmaceuticals supports the Foundation.

During the first year, awards of up to $20,000 have been made to over 50 individuals. No awards have been made to a pharmacist.

I recently had the opportunity to speak with Keith Campbell, R.Ph., who is one of the five persons to sit on the Board of Trustees for the Foundation. Mr. Campbell stated that the lack of awards to pharmacists was directly related to the fact that of the hundreds of applications received, only four had come from pharmacists.

Please let your membership know about this opportunity.

Requests for grant applications should be directed in writing to the Foundation at the address below.

Diabetes Research and Education Foundation
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Bridgewater, New Jersey 08807-9998
Attn: Herbert Rosenkilde, M.D.
Executive Director

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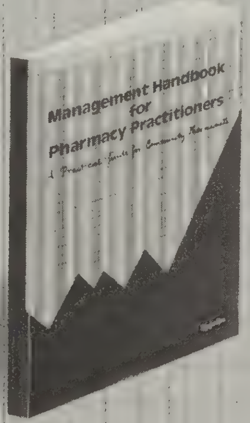

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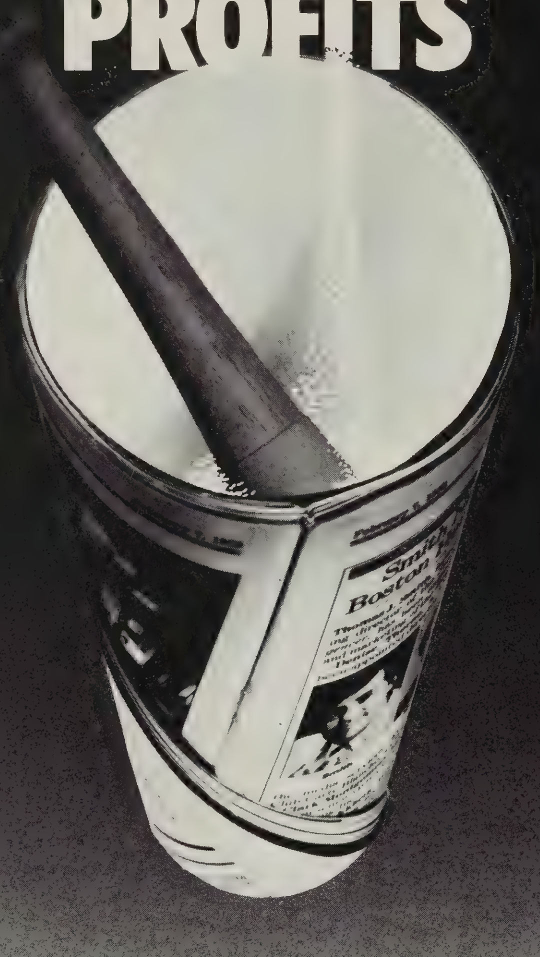

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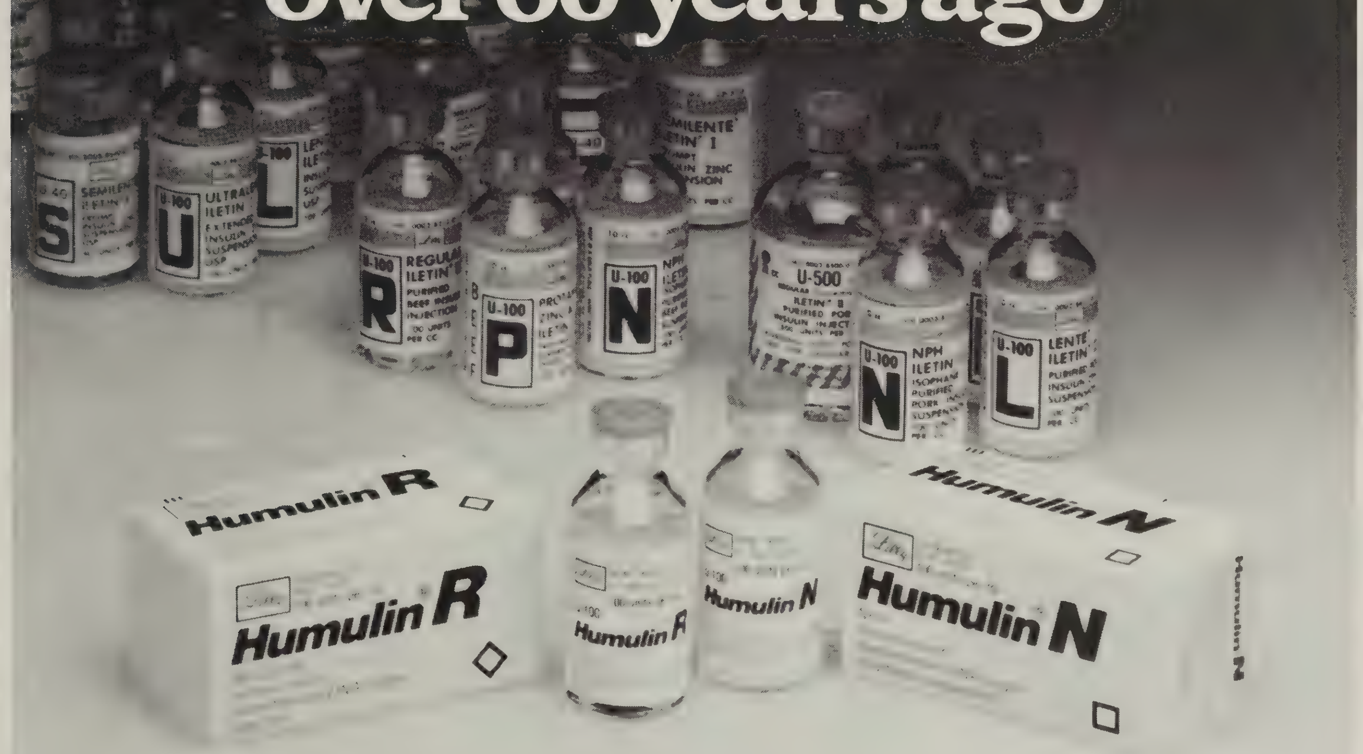

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IN DIABETES CARE

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SCOPE

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Advising Consumers On Hard Contact Lens Solutions

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Goals

The goals of this lesson are to:

1. discuss solutions used in the care and wear of hard contact lenses;
2. explain how to advise contact wearers on the proper use of these solutions.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. identify solutions intended for use with hard contact lenses;
2. explain the proper techniques for using these solutions.

in the service of pharmacy

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The purpose of this SCOPE lesson is to discuss the various solutions intended for use with hard contact lenses. There are five major subheadings of hard contact lens solutions. These include wetting solutions, cleaning solutions, soaking solutions, lubricants and combinations of the above. These solutions are defined, and their uses categorized. Specific consumer advice is also presented. Solutions for use with soft contact lenses will be discussed in next month's lesson.

The term "contact lens" is a misnomer. These lenses do not actually come in contact with the cornea. Instead, they float on a layer of tears (or commercial lubricating solution if tear secretion is inadequate). Therefore, contact lens solutions provide comfort for individuals who choose to wear lenses rather than spectacles.

A potential problem associated with hard contact lens use is decreased oxygen supply to the cornea which may cause corneal irritation. Unless measures are taken to correct this in susceptible lens wearers, they may experience intense physical discomfort. To alleviate this problem, a variety of solutions specifically developed for the care for these lenses and their preparation for insertion into the eye are available.

The Lens Solution Market

The OTC contact lens solution market is extremely competitive and highly subjective. Various manufacturers of contact lens products have successfully created strong brand loyalty to their solutions. Contact lens wearers have been taught to rely heavily on the advice of their lens fitters.

Manufacturers have attempted to acquire customers by supplying samples of contact lens solutions to ophthalmologists, optometrists and opticians who are the key advisors on which products are best suited to specific applications. Most contact lens wearers receive an introductory package of sample materials and products when their lenses are initially fitted. They generally will continue to use those brands.

There is very little difference between commercially available products from *within the same class*. After individual bias is removed, products in each class are basically interchangeable with others intended for the same purpose. However, products intended specifically for hard or soft lenses are not interchangeable with each other.

Most manufacturers are now working to develop products that can be used interchangeably for both hard and soft lenses. Several have been marketed that are useful for soft and hard lenses, and the newer gas permeable lenses. However, the two basic categories of contact lens solutions that are currently available are those primarily for hard lenses, and those that are used for soft lenses.

Legal Guidelines

Legally, contact lens solutions are regulated by the Device Section (rather than the Drug Section) of the Pure Food, Drug and Cosmetic Act. Manufacturers are required to test all their products on the various commercially available soft contact lenses before they can claim that the product is safe. They must also list the names of the specific types of lenses on the label. Before a consumer selects a brand of soft contact lens solutions, he can readily determine if the product is safe for his type of lens.

Contact Lens Care

The care of hard contact lenses begins when they are removed from the eye. The wearer must first clean and rinse the lenses. Plain tap water can be used for cleaning and rinsing hard lenses, but not soft lenses. After the cleaning solution and debris have been rinsed off, the lenses are soaked overnight. The lenses are then wetted before insertion into the eye. A list of ingredients contained in various contact lens solutions appears in Tables 1 and 2.

Wetting Solutions

Wetting solutions are agents that facilitate the spread of fluid over the surface of a solid material. Cohesion and adhesion are two physical properties which determine whether an item is hydrophobic (water-repelling) or hydrophilic (water-attracting).

Cohesion is the force of attraction between two molecules of the same substance. For example, iron molecules are strongly cohesive with other iron molecules, and water molecules are strongly cohesive with other water molecules. But iron molecules are not cohesive with water.

TABLE 1

Ingredients in Contact Lens Solutions and Their Functions

BUFFERS:
- Boric Acid (BA)*
- Sodium bicarbonate ($NaHCO_3$)
- Sodium borate (NaB)
- Sodium hydroxide (NaOH)
- Sodium phosphate(s) (NaP)

CHELATING AGENT:
- Ethylenediamine tetraacetic acid (EDTA)

DETERGENTS:
- Octylphenoxyethanol (OCT)
- Tyloxapol (TYL)

ISOTONICITY AGENTS:
- Boric acid (BA)
- Potassium chloride (KCl)
- Sodium chloride (NaCl)

PRESERVATIVES:
- Benzalkonium chloride (BCl)
- Chlorhexidine (CH)
- Phenylmercuric nitrate (PMN)
- Sorbic acid (SA)
- Thimerosal (TH)

SURFACTANTS:
- Bis-2-hydroxyethyl tallow ammonium chloride (BTA)
- Nonoxyl 15 (N15)
- Polyoxyl 40 (P40)
- Polysorbate (Polyoxyethylene) 21 (P21); 80 (P80)
- Poloxamer 407 (P407); 188 (P188)
- Polyvinyl alcohol (PVA)
- Povidone (polyvinylpyrolidine) (PPP)
- Tris-2-hydroxyethyl tallow ammonium chloride (TTA)

VISCOSITY AGENTS:
- Hydroxyethylcellulose (HEC)
- Hydroxypropyl methylcellulose (HPM)
- Methylcellulose (MC)
- Polyethylene glycol (PG)
- Polyvinyl alcohol (PVA)
- Propylene glycol (PRG)

*The abbreviations within parentheses are to simplify Table 2. They are not the chemical formulae for the compounds listed.

TABLE 2

Commercially Available Hard Contact Lens Solutions

WETTING	**INGREDIENTS***
Barnes Hind	PVA, BCl, EDTA
Contique	PVA, BCl, EDTA, HPM
hy-FLOW	PVA, BCl, EDTA
Liquifilm	PVA, BCl, EDTA, HPM
Visalens	PVA, BCl, EDTA, HPM
CLEANING	
Boston Lens Cleaner	surfactant/friction agent
Clens	?, BCl, EDTA
Contique	?, BCl
d-film	?, BCl, EDTA, P407
Gel Clean	?, TH
LC-65	?, TH, EDTA
Lensine	?, BCl, EDTA
Miraflow	?, P407
Opti-Clean	?, P21, TH
Titan	?, BCl, EDTA
SOAKING	
Boston Lens Conditioning Solution	PVA, HEC, CH, EDTA
Contique	BCl, EDTA
Soakare	BCl, EDTA
Soquette	PVA, BCl, EDTA
WETTING AND SOAKING	
Barnes Hind	PVA, PPP, BCl, EDTA, HEC, OCT
Contique Dual-Wet	PVA, BCl, EDTA
Soaclens	TH, EDTA
Wet-N-Soak	PVA, BCl, EDTA
CLEANING AND SOAKING	
Barnes Hind	?, BCl, EDTA
Clean-N-Soak	?, PMN
Contique	?, BCl, EDTA
duo-Flow	P188, BCl, EDTA
Visalens	?, BCl, EDTA
WETTING, CLEANING AND SOAKING	
Contactisol	BCl, EDTA, HPM, N15
Lensine 5	PVA, BCl, EDTA, P407, HEC, PG
Lens-Mate	PVA, BCl, EDTA, HPM
One Solution	?, BCl, EDTA
Total	PVA, BCl, EDTA
ADJUNCT SOLUTIONS (for use directly into the eye)	
Adapt	PPP, TH, EDTA
Adapettes	PPP, TH, EDTA
Aqua-Flow	BCl, EDTA
Blink-N-Clean	P40, PG, CHL
Clerz 2	P407, EDTA, SA, HEC
Comfort drops	?, BCl, EDTA
Lens Lubricant (B&L)	PPP, TH, EDTA
Lens-Wet	PVA, TH, EDTA
Pre-Sert	PVA, BCl

*See Table 1 for explanation of ingredients.
? = contains unidentified ingredient(s)

The second physical factor, **adhesion** is the force of attraction between molecules of different substances. If the force of adhesion between molecules on the surface of a drop of water and molecules on the surface of another substance is greater than the force of cohesion, the water will wet the substance and render it hydrophilic. If not, water will bead up on the surface (like rain drops on the hood of a freshly waxed automobile) and the substance is said to hydrophobic. This occurs with hard contact lenses and the cornea, both of which are hydrophobic.

Wetting solutions make the hydrophobic contact lens surface more hydrophilic. This increases the lubricating and cushioning effect between the cornea and the lens, and between the lens and the eyelid.

Wetting solutions provide a viscous coating over the lens surface so that it does not come in direct contact with the finger during insertion. This prevents oily sebaceous deposits of the skin from transferring to the lens. These solutions also help to stabilize the lens on the fingertip to promote easier insertion. Without a wetting solution, water would not wet the lens and the lens would cause pain and discomfort when placed on the eye.

Tears contain various protein and polysaccharide complexes that assist in wetting contact lenses. But this is not adequate until five to fifteen minutes after the lens is inserted. Wetting solutions accomplish this until the tears take over.

Wetting solutions also serve as a cushion between the lens and the cornea, and prevent sudden movements of the lens when the individual turns his head quickly.

The most common ingredients used in wetting solutions are polyvinyl alcohol, methylcellulose, and other celluose derivatives which increase the viscosity and aid in the cushioning effect. The most commonly used preservative has been thimerosal. Manufacturers are moving toward sorbic acid which is less irritating and sensitizing.

To review, wetting solutions are used prior to inserting hard lenses. They provide a hydrophilic surface to the lens, promote the spread of tears, and prevent the initial discomfort that would be experienced with hard lenses. They also serve as a cushion between the cornea and the lens, and between the lens and the eyelid.

Cleaning Solutions

Human tears consist of a number of substances secreted by various glands from within the structures of the eye and eyelid. These include hydrophobic oils and proteinaceous residues which adhere to lenses. While they serve a useful purpose, they also provide a media for bacterial growth. Over time, they harden on the lens surface into rough deposits that irritate the cornea and the eyelids. If allowed to accumulate, they may cause corneal abrasion and increase chances for infection. The lenses may become cloudy, decreasing visual acuity.

Cleaning solutions contain detergents as their main ingredient, most commonly nonionic surfactants. These agents emulsify fats and oils and help solubilize other substances. Most cleaning solutions are used when the lens is out of the eye. There are a few solutions that are indicated specifically for application to the lens while it is inserted. Products not labeled specifically for such use should not be placed directly into the eye.

Cleaning solutions enhance the removal of debris through their detergent activity. Those intended for use after the lens is removed must be thoroughly rinsed off before the lens is reinserted to avoid irritation.

The two most widely used nonionic detergents are octylphenoxyethanol and tyloxapol. Other ingredients include surfactants such as bis-2-hydroxyethyl tallow ammonium chloride (BTA), polyoxyl 40, polysorbate 80, polyoxamer 407, polyvinyl alcohol, povidone, and tris-2-hydroxyethyl tallow ammonium chloride. Buffering agents include boric acid, sodium borate, and the sodium phosphates. Isotonic agents are sodium and potassium chlorides.

Some cleaning solutions contain agents that increase their viscosity. These include the cellulose derivatives, polyethylene glycol, and propylene glycol. All cleaning solutions contain a preservative. Benzalkonium chloride, thimerosal and sorbic acid are the mainstays. Sorbic acid reportedly causes less irritation than thimerosal and its use is increasing, especially in solutions intended for soft lenses. The remaining ingredient in hard lens cleaning solutions is the chelating agent, ethylenediamine tetraacetic acid (EDTA). This will be discussed shortly.

Benzalkonium chloride is a cationic, surface active, quaternary ammonium germicide effective against many gram-positive organisms and a few gram-negative varieties. The exact mechanism for the antimicrobial action of benzalkonium chloride has not been determined. It is theorized that its surface active property interferes with the membrane integrity of susceptible organisms, or alternatively, that it interferes with respiration and glycolysis (carbohydrate breakdown) in susceptible organisms. In either instance, bacterial growth cannot proceed and replication is inhibited.

Benzalkonium chloride can also serve as a wetting agent because it lowers the surface tension of water. However, quaternary ammonium compounds have both a hydrophilic (cationic) portion and a hydrophobic (nonpolar) portion. When the hydrophilic end aligns with the water in tears, it can actually form another hydrophobic layer between the water molecule and the hydrophobic hard lens, making the lens even less wettable. Benzalkonium chloride is, therefore, contained in contact lens solutions only for its germicidal activity. It is used at the lowest effective strength, 0.12% (1:750).

EDTA is a calcium chelater. This means that it binds with calcium ions. However, it is used in contact lens solutions because it slightly decreases the integrity of microorganisms cell walls, and increases their permeability for penetration by benzalkonium chloride. This enhances the germicidal activity of the quaternary ammonium compound, benzalkonium chloride.

Hard lenses may be cleaned by different techniques. **Spray cleaning** involves placing the lenses in a perforated holder that is held under running water which dislodges accumulated debris. **Hydraulic cleaning** utilizes a plastic holder containing separate baskets. A plunger device is pushed up and down, forcing a cleaning solution over and around the lenses.

Most hard lens wearers use **friction cleaning**. This involves rubbing the lenses between two fingers in a rotating manner, or placing the lens in the palm and rubbing with a finger from the other hand. Either way, a cleaning solution or gel is used on both sides of the lens at the same time.

A fourth method, **ultrasonic cleaning**, is the best but most expensive. It is done in the fitter's office rather than at home. The lenses are placed in a water bath and ultrasonic waves are passed over them which dislodge and remove debris.

In summary, cleaning solutions are used after removal of hard lenses to enhance elimination of mucus, protein, oils and debris, and to keep foreign material from adhering to the lenses. To lessen irritation, the individual must rinse the solution off completely before reinserting the lenses. Because cleaning solutions must be rinsed off, many manufacturers market cleaning solutions that are appropriate for both hard lens and soft lens use. This mainly involves lowering the concentration of the detergent.

Soaking Solutions

For the most part, soaking solutions consist of preservatives. They are used for holding the lenses between wearings. They are intended to prevent bacterial contamination of the lenses during storage, to dilute any remaining cleaning solution, and to leach out protein and mucus that the cleaning solution did not remove. Mucus and debris left on lenses overnight may also harden if the lenses become dry. Soaking solutions prevent this. They also help maintain the wetability of hard lenses and aid them in retaining their shape during storage.

Even though they are hydrophobic, hard lenses can absorb 1 to 3% of their weight in fluids. They dehydrate slightly when exposed to air, then rehydrate when placed in a soaking solution or back into the eye. If they are reinserted in dehydrated form, they may extract fluid from the cornea. This can cause discomfort and increase the chance for bacterial infection. Dehydrated lenses are also flatter, so vision may be impaired until the lenses become rehydrated.

Soaking solutions should be poured fresh each time they are used. Any solution remaining in the storage chamber after the lenses have been removed should be flushed out before new solution is added. Reusing soaking solutions negates their effectiveness.

Lubricants And Viscosity Agents

These agents are similar to wetting solutions. Some are used prior to insertion for cushioning the lens against the cornea. Others are used to increase comfort while the lenses are being worn. It is claimed that these solutions clean and rewet the lens while it is still in the eye. Since hard lenses can absorb mucus and salts onto their surface to possibly cause blurred vision and enhance the chance for infection, these agents prevent potential build-up from occurring.

Most authorities and manufacturers prefer polyvinyl alcohol to the cellulose derivatives for both their lubricating and wetting solutions. The cellulose derivatives reportedly may interfere with regeneration of corneal epithelium in a few individuals. Polyvinyl alcohol is also considered to be a more effective wetting agent.

Multipurpose Hard Lens Solutions

Because of the large number of solutions involved in the care of hard lenses, there has been a trend in recent years toward developing multipurpose products. However, there is some controversy associated with the use of these solutions. Their proponents argue that they save the consumer money and are more convenient to use. Opponents advise against their use claiming that good lens cleaning solutions must contain enough surfactant and detergent to do the job. Trying to make soaking and wetting solutions of them requires lowering the concentrations of ingredients to the point that they do not contain appropriate amounts of cleaner. To do so will result in a solution that will irritate the eye.

There is less controversy associated with combination soaking and wetting solutions because these are basically similar. Opponents to their use state that the ingredients must perform divergent functions. The high concentration of preservatives in soaking solutions needed to kill bacteria can be irritating when used as wetting agents or lubricants. The high concentration of viscosity agents needed for wetting and lubricating can cause lenses to become "gummy," and result in discomfort if used for overnight storage. The anionic detergents needed for cleaning can cause irritation if they are placed directly into the eye. Millions of individuals disagree with these objections and have no problems with multipurpose solutions.

Adjunct Solutions

Pre-insertion solutions are intended to be used directly into the eye to prepare it for lens insertion. Most are highly viscous substances that decrease corneal sensitivity to lens application. Consumers should be reminded that the viscous solutions may cause blurred vision until they are diluted by tears. They should, therefore, not be applied to the eye immediately before driving or other events which require visual acuity.

Conditioners are used directly in the eye when tears are unable to sufficiently wet or cushion the lenses. They can be applied periodically, three to four times a day.

Consumer Advice

Contact lens wearers should inform their fitter if they experience sharp eye pain, excessive watering, persistent irritation or inflammation of the eye, sudden changes in vision, or spectacle blur that does not clear overnight. Spectacle blur is a phenomenon in which hard lenses worn for a number of hours cause corneal edema. This changes visual acuity for several minutes to several hours after lens removal until the eye returns to normal.

Since the air supply to the cornea is reduced during sleep, it is best to not insert hard lenses immediately upon awakening. When the eyelids are closed for a period of time, the cornea may become slightly swollen. Therefore, persons should wait ten to fifteen minutes before inserting the lenses. Occasionally during the day, they should blink hard and hold the eyes closed for several seconds to enhance better tear flow.

Placing a lens into the mouth to wet it before reinserting it should not be done because the oral cavity is laden with bacteria. There is a possibility that pathogenic organisms will be introduced into the eye. Also, the person might swallow the lens.

The largest group of contact lens wearers is women between the ages of eighteen and twenty-four. Most of these women are also good cosmetic customers. It is estimated that they spend more money on cosmetics than non-wearers, so one topic of importance to consumer counseling regards restrictions on cosmetic use.

Aerosol hairsprays should be used *before* inserting contact lenses, and preferably should be applied in another room to avoid particles of the spray from attaching to the lenses.

Wearers should wash their hands thoroughly before handling the lenses, regardless of whether the lenses are the soft or hard variety. The hands should be thoroughly rinsed because soap can leave a residue on the lens.

Lenses should be inserted before applying makeup because oily substances in these preparations can stick to the fingers and smudge the lenses when they are handled. Conversely, lenses should be removed before removing makeup. Many ophthalmologists advise lens wearers to purchase makeup in the smallest

TABLE 3

Consumer Advice

- Do not use dishwashing detergents to clean hard lenses. (They may cause physical changes in the surface of the lens.)
- Do not use saliva to re-wet contact lenses. (The mouth is laden with bacteria which can be transferred to the lens.)
- Do not wipe hard lenses dry with tissue. (This may cause scratching.)
- Keep the contact lens solution tightly sealed between uses, and do not touch the dropper tip to any surface. (This reduces the chance of contaminating the solution.)
- Clean hard lenses as soon as they are removed from the eye. (This prevents deposits from becoming difficult to remove.)
- Follow proper sanitary procedures while inserting, removing, or caring for contact lenses. (This increases their life and reduces the chance for contaminating the eye.)
- Do not re-use any contact lens solution. Always use fresh solution. (This prevents growth of microorganisms in the solution and transfer to the eye.)
- Do not use any contact lens solution beyond the expiration date on the bottle. (It may be decomposed or contaminated.)
- Contact your fitter if any of the following become persistent or excessively irritating:
  - —Burning, itching, stinging or watering of the eye
  - —Redness or dryness of the eye
  - —Reduced ability to see clearly
  - —Spectacle blur that does not clear up overnight.

  Any of these may be signals of eye damage or corneal hypoxia.

containers. Once opened, the longer it sits around, the greater is the chance for bacterial contamination which can be transferred to the lenses.

Mascara and pearlized eye shadow should be avoided by women wearing hard lenses. Particles from these types of makeup can easily flake into the eye and cause considerable irritation and, possibly, corneal damage. It is less of a problem with the soft lenses, because soft lenses adhere to the cornea and particles do not readily penetrate underneath them.

Contact lens wearers who notice that their eyes are bloodshot should not use OTC vasoconstrictors without checking with their physician. Vasoconstrictors may mask a symptom that should be evaluated by a physician and treated. A summary of other important points of consumer advice for contact lens wearers is presented in Table 3.

This series on contact lenses and their solutions will conclude next month. Products intended specifically for soft lenses, and questions about lens solutions that are asked of pharmacists will be presented.

A Pharmacist Letterwriter's Guide to Congress

Today's congressional calendar no longer contains the frequent recesses—called "district work periods"—that used to allow Members of Congress to keep in close personal touch with concerned constituents. As a result, Senators and Representatives now most often learn about the views of the voting public through LETTERS, rather than face-to-face discussions.

Writing effective letters to your Senators and Representative is not a difficult task. Here are a few guidelines that will make writing to your Members even easier.

- Write on your personal or business stationery, if possible. And sign your name over the typed signature at the end of your message.
- Be sure that your return address is on your letter, not just on the envelope. Envelopes sometimes get misplaced before the letter is answered.
- Identify the subject of your letter clearly. Give the name of the legislation you are writing about. Use the appropriate House and/or Senate bill numbers, if possible.
- State your reason for writing. Your own personal experience is your best supporting evidence. Explain how the legislation would affect you or your family, business or profession—or what effect it would have on your state or community.
- Avoid trite phrases and sentences. Cliches make your letter appear to be part of an organized "pressure" campaign—and, thus, minimize the impact of your message.
- Be reasonable. Don't ask for the impossible. Don't threaten. Don't say, "I'll never vote for you unless you do. . . ." That will not help your cause; it may harm it.
- Be constructive. If a bill deals with a problem that you admit exists, but you believe that the bill takes the wrong approach toward solving that problem, explain what you believe the right approach is.
- Don't pretend to wield vast political influence. Write your Member as an individual, not as a self-appointed spokesman for your neighborhood, community or industry. Unsupported claims of political influence only cast doubt upon the views you express.
- Don't become a constant "pen pal." Quality, rather than quantity, is what counts. Don't try to instruct your Members on every issue that comes up. And don't nag them if their votes do not reflect your thinking every time. Remember, each Member has to consider all of his or her constituents and all of their points of view.
- Concentrate on your own delegation. Your district's Representative and your state's Senators cast your votes in Congress and want to know your views. Don't undertake writing to all 435 Representatives and all 100 Senators, who cast their votes in the interests of other districts and other states.
- Ask your legislators to explain their position on the issue in reply. As a constituent, you're entitled to know how and why your Members feel as they do.
- Consider timing. Try to communicate on a bill while it still is in committee. Your Senators and Representative usually will be more responsive to your views at that time—rather than later on, when the bill has already been shaped by a committee.
- Thank your Members if they please you with a vote. Everybody appreciates a complimentary letter—and remembers it. On the other hand, if they displease you, don't hesitate to communicate your displeasure—that, too, will be remembered.

Suggested Addresses and Salutations

The Honorable John Doe
House of Representatives
Washington, D.C. 20515
Dear Mr. Doe:

The Honorable John Doe
United States Senate
Washington, D.C. 20510
Dear Senator Doe:

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Piroxicam: Imminent Hazard to the Elderly?

by Peter P. Lamy, PhD

Introduction

The Health Research Group (a Nader group) of Washington, DC, has asked HHS Secretary Otis Bowen to ban the use of piroxicam (Feldene) for people over 60 years of age. The group claims that, based on FDA data, "FDA has received a total of 2,261 non-fatal and 182 fatal adverse reaction reports associated with the drug's use. These figures include 687 nonfatal cases due to severe gastrointestinal toxicity and 99 deaths in which there was stomach and intestinal bleeding, ulcers, intestinal perforation, hematemesis, or melena". The group continues that "virtually all of the gastrointestinal deaths of 71% of the nonfatal reactions due to GI toxicity from Feldene . . . occurred in persons 60 years of age and older". It is estimated that 1.75 million elderly in America now receiving this drug are at risk to developing life-threatening GI reactions.

Two-thirds of all adverse drug reactions reported to the Committee on Safety of Medicines (the British FDA) are due to NSAIDs. The CSM has announced that it will investigate 77 known fatalities due to this drug. The CSM has received 457 reports of upper GI bleeding associated with piroxicam since 1970 and 195 reports associated with keptoprofen since 1971. The corresponding figure for indomethacin since 1965 is 419. Indeed, the CSM is reviewing the therapeutic/toxicity profiles of all existing NSAIDs, some of which have consequently been withdrawn voluntarily (two), some of which were withdrawn via regulatory action (four) and the use of still others has been limited (one).

Pfizer, maker of Feldene, disputes the data and claims that all NSAIDs can cause severe GI reactions and that the individual reports should be viewed in context of the total number of prescriptions issued.

What are the facts?

The population at risk to serious side effects from NSAIDs is rapidly growing as the population is aging. The number of prescriptions for NSAIDs rises with age, but the incidence of all side effects rises disproportionally with age. Most of the side effects of NSAIDs are inevitably associated with the characteristic properties of these drugs which cause them to act therapeutically, i.e., the inhibition of prostaglandin biosynthesis.

The widespread use of NSAIDs is accompanied by varying degrees of GI intolerance. However, it needs to be remembered that elderly with rheumatoid arthritis develop gastric ulcers or erosions significantly more often than do younger RA patients.

Is piroxicam less safe than other NSAIDs? All NSAIDs are remarkably safe for people under 60, as documented by many studies. Piroxicam has been judged safe in a number of literature reviews and, in following a small number of elderly patients being treated with piroxicam in Baltimore, it was found to be very safe.

On the other hand, a study showed that the steady state plasma concentration of piroxicam in elderly (mean age 70.6 years) women was about 60% higher than in young women or even elderly men, probably because elderly women eliminate piroxicam more slowly.

One study showed a significant relationship between NSAID consumption and upper GI bleeding in elderly patients admitted to a hospital. Gastric ulcer was involved in 24% of patients, duodenal ulcer in 21%, and esophagitis in 12%. In a similar study involving patients 55 years or older, gastric ulcer was the most common cause of bleeding in 29% of patients, duodenal ulcer in 21%, hemorrhagic gastritis in 17%, and esophagitis in 14%. A retrospective study of elderly patients selected for gastroscopy showed a significant association between UGI pathology and NSAID ingestion. In a prospective gastroscopic study of the effects of NSAIDs, it was shown that all NSAIDs cause gastric lesions in about 30% of all patients, the incidence rising about 2.5 times when more than one drug was used. In the UK, there has been an increase in prescribing of NSAIDs to all age groups, yet the percentage of patients with perforations taking NSAIDs only increased in those 65 years old and older. In a retrospective study comparing 269 patients with perforated ulceration and 269 age/sex matched controls, a highly significant association between age and perforations was found for those 65 years and older, but not for those younger than that. Furthermore, a highly statistically significant correlation between the annual number of patients aged over 65 with perforated ulcers taking NSAIDs and the annual number of prescriptions issued for these drugs in the region was shown. No such correlation was found for the patients under 65 years. The largest number of patients were women over 65, and the authors suggested that elderly, especially elderly women,

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are unduly susceptible to NSAID-associated peptic ulcer perforation.

Particular caution ought to be employed when piroxicam is used for elderly patients. In one British hospital, this drug was responsible for 3% of all ulcers over a four month period, and there are indications that there is an incidence of up to 29% of lesions caused by this drug, including a consistent prevalence of perforations, possibly because of its long half-life. Most recently, similar results were obtained in a study in England that matched data on patients with peptic ulceration with the number of prescriptions issued in a particular region. Very few of the elderly patients had a history of peptic ulceration. Data for piroxicam and keptoprofen showed an unusual high incidence of ulceration due to these drugs.

Conclusion: NSAID therapy is often related to gastrointestinal disorders in the elderly, due to altered secretory and motor function, as well as structural changes in the aging stomach. The incidence of new cases of peptic ulcer is high in the elderly, who are particularly at risk since GI hemorrhage may present without pain and can, therefore, be overlooked. Death from peptic ulcer occurs predominantly in late life. Mortality reaches 25% in those 80 years and older. It has been estimated that the relative risk of an older patient taking an NSAID of developing an ulcer is 4.5 times that of a person not using one of these drugs. While the risk for each drug has not yet been established, it does appear that piroxicam, for a number of reasons, may pose the greatest risk.

SOME RECOMMENDATIONS

1. Do not use any of the NSAIDs unless good prescribing information for the elderly is available on a sufficient number of studies which have included the very old and females.
2. Perhaps analgesics should be allocated a more important role in the management of some of the arthritic diseases.
3. The convenience of a once-a-day dose may have less relevance in a painful condition where many patients probably like access to a drug with a relatively fast onset of action more than once in every 24 hours. A once-a-day dose may, indeed, lead patients to overuse the medication.
4. Evening doses are most effective in managing night or morning pain. On the other hand, morning and noon doses are better tolerated as far as side effects are concerned.
5. To overcome GI effects, always administer with food, even if pharmacokinetic data indicate otherwise.
6. Identify the patient most at risk to GI problems. Risk increases:
    a. With advancing age
    b. With female gender
    c. In underweight and malnourished patients
    d. In patients with reduced kidney function
    e. With increased half-life of the drug
    f. In patients with concurrent diuretic use
    g. In patients receiving multiple NSAIDs
    h. In patients receiving multiple drugs with gastric erosive properties, including the OTC NSAIDs

---

Guide to Immunizations

"An important step in keeping your children healthy is to make sure they receive the immunizations they need, and at the right ages," according to the American Academy of Pediatrics (AAP).

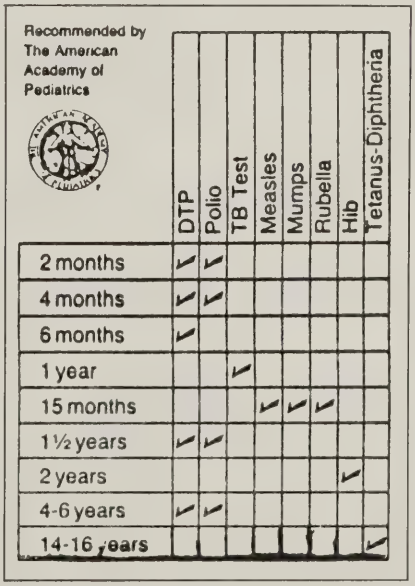
The AAP offers the following guidelines for scheduling immunizations:

At 2 months: DTP and Polio; at 4 months: DTP and Polio; at 6 months: DTP; 1 year: TB test; 15 months: Measles, Mumps and Rubella; 1½ years: DTP and Polio; 2 years: Hib; 4–6 years: DTP and Polio; 14–16 years: Tetanus-Diphtheria.

The Academy suggests that parents maintain their own immunization chart for each child, recording when and where the various vaccinations were given. The pediatrician or family physician should be consulted about which vaccines are needed.

A new vaccine was recently added to the chart of immunizations endorsed by the AAP. It protects against Haemophilus influenzae type b ("Hib"), a bacterium that can cause bacterial meningitis and other serious invasive infections in children, particularly under the age of six. The vaccine is called b-Capsa I and it has been available since April, 1985.

The AAP recommends that all children receive a Hib shot at two years of age. For children who do not receive it then, vaccination up to the fifth birthday is recommended. The AAP also recommends that vaccination against Hib be considered for children in the 18–23 month age group if they are at high risk to Hib. High risk children include those attending day care centers and nurseries.



Recommended by
The American
Academy of
Pediatrics

	DTP	Polio	TB Test	Measles	Mumps	Rubella	Hib	Tetanus-Diphtheria
2 months	✓	✓						
4 months	✓	✓						
6 months	✓							
1 year			✓					
15 months				✓	✓	✓		
1½ years	✓	✓						
2 years							✓	
4-6 years	✓	✓						
14-16 years								✓

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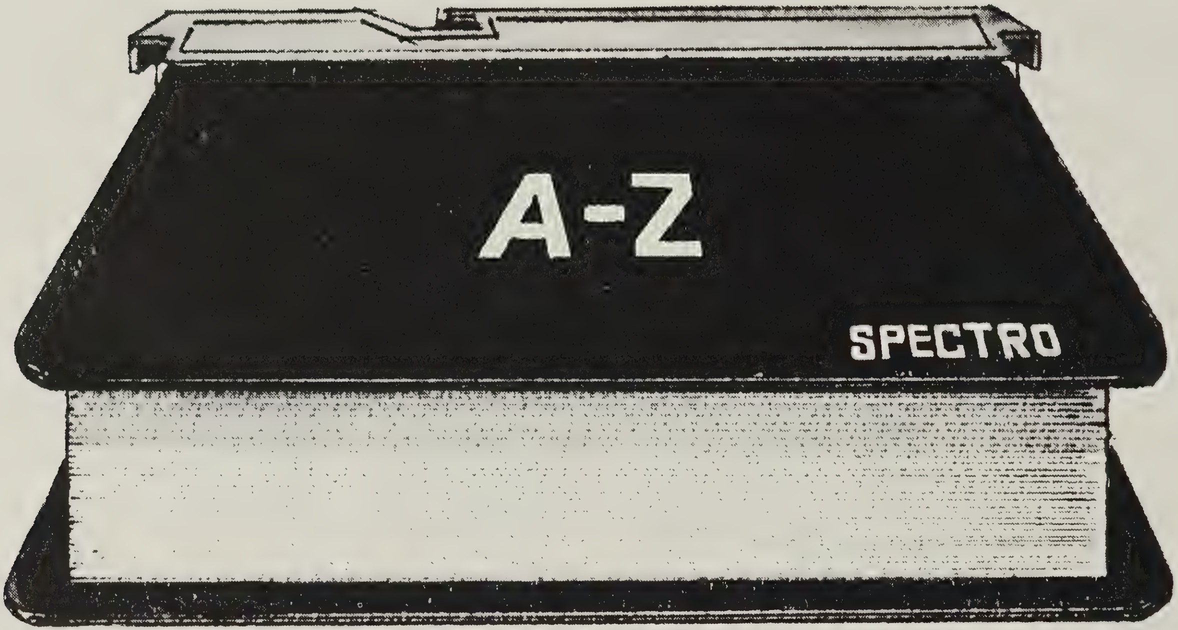

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EMPLOYEE—EMPLOYER RELATIONS COMMITTEE

The purpose of the committee is to deal creatively with the issues in Maryland Pharmacy employer and employee relations. This Committee of the Association is made up of individuals from a wide variety of practice settings. We are asking for input on current employment issues from all segments of the profession.

Suggested Employment Agreement Considerations

The Employer-Employee Relations Committee feels that a clear understanding of the Employment Relationship is necessary to prevent misunderstanding by either the Employer or Employee Pharmacist. The Committee feels an agreement between the Employer and Employee Pharmacist, whether it be an informal agreement or highly structured formal contract, is necessary for a mutually satisfying relationship.

The Committee therefore presents, as a service to the members of the Maryland Pharmaceutical Association, a list of job-related items which should be considered and discussed at the time of employment by the employer and employee pharmacist.

1. *Job Description.* The Pharmacist should have a clear understanding of the duties, responsibilities, and authorities that will be expected as part of the employment. In some cases employer may wish to provide a ''Policy Manual'' that will outline operating procedures for the employee pharmacist. This will allow both employer and employee to measure performance against an established criteria.

2. *Length of Employment.* In most instances the length of employment will be indefinite. However, the following should be discussed:

   a. Length of the ''Probationary Period'' if any.
   b. The duration of the agreement, if any.
   c. The conditions under which the agreement may be re-negotiated.

3. *Compensation.* As part of the compensation package, some of the following may be considered:

   a. salary (hourly or weekly)
   b. overtime
   c. Bonus and or profit sharing
   The method of arriving at such a figure should be pre-determined and agreed upon.

4. *Benefits.* Without intending to be all inclusive the following list of possible employment benefits is provided and if available should be clearly understood:

   a. vacation
   b. sick leave
   c. professional society membership
   d. continuing education
   e. health insurance
   f. Life insurance
   g. professional liability insurance
   h. income protection insurance
   i. retirement plan
   j. stock purchase options
   k. personal purchases—employee discounts
   l. professional attire
   m. court time (jury duty, witness)
   n. funeral leave

5. *Schedule.* While allowing for flexibility, an understanding should be reached regarding the general hours to be worked, shifts, and procedures for requesting alterations of the standing schedules. In addition, it is helpful to know specifically which day will be considered holidays.

6. *Practice Limitation.* In some practices an employee may wish to stipulate that the employee pharmacist may not work for another employer in a relief or part-time position.

7. *Arbitration of Disagreements.* It may be helpful to provide a description of the manner in which disagreements can be resolved. The employer-employee relations forum will not serve as a formal arbiter, but is available to make recommendations for arbitration.

8. *Termination.* The agreement may be formal or informal, but the amount of notice (and or severence pay) should be specified.

In conclusion, we cannot emphasize enough the importance of regular, open communication between the employer and employee.

Ipecac Syrup—Friend or Foe?

Gary M. Oderda, Pharm. D., M.P.H., Director Maryland Poison Center

Introduction

Ipecac syrup is the emetic of choice to remove toxic agents from the stomach and prevent absorption. Since its approval for purchase of appropriately labeled one ounce containers without prescription approximately twenty years ago a major goal of poison center public education efforts has been to get a bottle of ipecac syrup into each young child's home. Ipecac syrup was used in 12.9% of the 730,224 cases collected by the American Association of Poison Control Centers data collection system in 1984.[1] In approximately half of these cases it was administered outside of a health care facility. Ipecac syrup was administered 9 times more frequently than was gastric lavage. Pharmacists should be aware of recent reports of ipecac syrup toxicity seen in bulimic patients who chronically take large doses. The position of the Maryland Poison Center (MPC) remains that ipecac syrup is both safe and effective when administered in appropriate doses for acute poisonings and should be present in the homes of all young children.

Use of Emetics

Management of the poisoned patient may involve provision of supportive care, prevention of absorption from the GI tract, hastening elimination and administration of antidotes. Ipecac syrup and gastric lavage are two commonly employed methods to remove agents from the GI tract to prevent absorption. With appropriate telephone supervision and follow up by a Poison Center or other health professional many mild poisoning cases are handled safely at home. Using ipecac syrup in this way prevents unnecessary emergency room visits. This decreases health care costs, prevents unnecessary utilization of services which can be used for those truly in need, and prevents the emotional trauma of an emergency room visit. If ipecac syrup is kept in the home, it can be given immediately after consultation with the Poison Center or health professional. This results in vomiting as soon as possible after the ingestion and maximizes efficacy. Administering ipecac syrup in this manner can result in vomiting occuring 30–60 minutes sooner than would have been possible either by going to an emergency room or going out to purchase ipecac syrup and returning home to administer it.

Toxicity

Two decades of non-prescription use has shown that single administrations of ipecac syrup in doses of 30 mL or less produces vomiting in excess of 95% of patients with only minor side effects. Diarrhea and sedation are commonly seen post ipecac induced emesis. Whether the drowsiness is a direct pharmacologic effect, is related to vomiting, or to the ingested agents, is unclear. Most reported cases of severe toxicity and death involve mistaken administration of the 14x stronger fluid extract of ipecac.[2] Since there is no official use for the fluid extract, it should no longer be present in pharmacies and errors of this type should not occur. Four additional case reports involve ipecac syrup.[2,3,4] In two of these an antiemetic drug was ingested, large doses of ipecac syrup were given, and vomiting did not occur. In one case a diaphragmatic defect was felt to be responsible for the fatality.[4] Ipecac syrup contains two major alkaloids, emetine and cephaeline.

The medical literature contains case reports of ipecac toxicity, including one fatality, in five bulimic patients abusing ipecac syrup to lose weight.[5,6,7] The pattern of use in the fatality involved daily use of three to four ounces of ipecac syrup over a three to four month period.[2] Lay publications have contained claims that Karen Carpenter's death, and that of another woman in Pennsylvania, were the result of ipecac poisoning from abuse in bulimia. To my knowledge substantiation of these claims has not been presented. A lawsuit has been filed in the Pennsylvania case alleging that the woman's death was the result of inappropriate labeling.

Proposed Changes

Several proposals have been made to decrease the problem of ipecac syrup abuse in bulimics including changing ipecac syrup to a prescription agent, requiring sale only by pharmacists or other health professionals, or changing the labeling to indicate the danger of repeated use.

In order to address ipecac syrup abuse in bulimic patients, one needs to determine whether a significant enough problem exists to require action. Only a small number of cases have been reported. Many of the patients who abuse ipecac have other significant medical problems as a result of their bulimia, abuse other diet preparations such as phenylpropanolamine, and abuse other laxatives as well. To blame their toxicity on ipecac syrup may be inaccurate. This line of reasoning could lead to the conclusion that nothing needs to be done. In my opinion that would be a mistake. Although substantiation of the number of patients who abuse ipecac syrup, and the toxicity resulting from this abuse, is not available, it is likely that it is greater than the number of reported cases and does require action.

In assessing the impact of decreasing availability of ipecac syrup, one must examine the effect on poisoned patients and the effectiveness of limiting abuse in bulimics. Limitation of ipecac availability would have a significant detrimental effect on poisoned patients. If ipecac syrup were a prescription agent, although it is true that parents of young children could be given a prescription and have it filled to keep in the home, it is likely that in many cases the prescription would not be given and in many others it would not be filled. Even with a continued education effort by the MPC to get ipecac syrup in the home in a significant proportion of cases it is not available even though it can be currently be purchased without prescription. Limiting sale to pharmacies would decrease availability during evening hours and on weekends. Would these changes prevent abuse by bulimics? Prescription status would make ipecac syrup more difficult to obtain. Through purchase via illicit channels, obtaining legitimate prescriptions, and forgery of prescriptions a limited supply would continue. Decreasing the availability would likely decrease but not prevent the abuse problem. Would this decrease in availability switch bulimics to other methods to induce emesis such as gagging, salt water and dishwashing detergents; all of which also have some associated toxicity?

Poison Center Position

It is the position of the Maryland Poison Center that any changes that would decrease availability of ipecac syrup would be detrimental to poisoned patients. The following is suggested as an alternate approach to the problem. First a warning should be prominently placed on ipecac syrup stating that it is not intended for repeated use and such use can be dangerous. This will inform abusers of the risk and should eliminate the problem of toxicity in those abusers not aware that such use will be dangerous. Will this stop all abuse? No. Some individuals will ignore the warning to obtain the desired benefit. It will prevent uninformed abuse. The second step would involve closer scrutiny of ipecac syrup sales. Attention should be placed on each individual attempting to buy multiple bottles at one time or individuals who purchase ipecac syrup frequently. The volume of sales of ipecac syrup is small enough that a pattern of abuse should be evident if the patient buys ipecac syrup from a single source.

Indications and Contraindications

Ipecac syrup is indicated for potentially toxic ingestions where a sufficient amount remains in the stomach. Several contraindications exist. Ipecac syrup should not be used if:

1. A caustic has been ingested. These strong acids and bases produces burns in the mouth and GI tract. Administering an emetic would reexpose these areas to the caustic and the force of vomiting could cause perforation.
2. The patient is lethargic or comatose. If vomiting occurs in these patients aspiration is likely.
3. The patient is seizing or if seizures are likely. If a seizure occurs while a patient is vomiting aspiration can occur.

Two additional areas are controversial. The first involves antiemetic ingestions. Vomiting can be induced in these patients if it is soon after the ingestion and the patient is not symptomatic. If symptoms are present or if the ingestion occured more than an hour earlier the patient should be lavaged. The final controversial area is when hydrocarbons such as gasoline and kerosene have been ingested. In most of these cases it currently is felt that inducing vomiting is not necessary since the toxicity seen is not produced by a direct effect of hydrocarbon absorbed from the GI tract.

Guidelines for Use

The MPC recommends the use of ipecac syrup at home in children 6 months of age or older. Safety and efficacy of ipecac syrup in children between 6 months and a year of age has recently been demonstrated.[8] Purchasers of ipecac syrup should be cautioned to always consult with the MPC or other health professional prior to administration.

The following initial doses are recommended:

6–11 months	10 mL
Children over 11 months	15 mL
Adults	15–30 mL

Fluids must be administered along with the ipecac. Any fluid besides milk is satisfactory. Amounts of 4 to 8 ounces in children and 12 to 16 ounces in adults are satisfactory. Vomiting generally occurs in approximately 20 minutes. If by that time the patient has not vomited the initial dose of ipecac syrup may be repeated.

Conclusion

Ipecac syrup is a safe and effective non-prescription emetic. It should be kept in the homes of all families with young children. Abuse of ipecac syrup by bulimics is potentially dangerous. Additional warnings and monitoring of sales should help to prevent further toxicity. Pharmacists should encourage the purchase of ipecac syrup by families of young children and educate them to use it appropriately after consultation with a Poison Center or other health professional.

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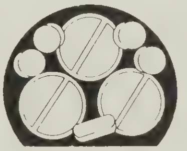
national scene

FDA Targets Teens

The Federal government, pleased with voluntary efforts by aspirin manufacturers and health care organizations such as APhA in warning parents of the reported link between aspirin use and Reye Syndrome, is focusing its attention this flu season on reaching teenagers. As parents have stopped giving aspirin to children with flu or chicken pox, teenagers who self-treat these ailments with aspirin have become the age group most at risk of contracting Reye.

A new Food and Drug Administration poster warns teenagers that "medications such as aspirin and aspirin-containing products may not be a good idea. A rare but dangerous condition called Reye Syndrome may develop in young people just when they appear to be recovering. Studies suggest a link between the development of Reye and the use of aspirin to treat the flu and other viral illnesses.

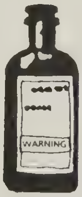
Medicare Cost-effective



A doctoral research study from the University of Texas claims to show that continuing drug coverage for Medicare patients after they have been discharged from the hospital would be cost-effective. The study, done by Earle W. Lingle, Jr., found that adding outpatient drug coverage would not increase overall expenditures.

Says Lingle, "Outpatient prescription drug costs could be absorbed by Medicare, providing more benefits and probably better health for the patients without spending more money." The reason? Lingle says that "The costs of outpatient drug reimbursements appear to be offset by reduced inpatient hospital service expenditures or that patients who maintain outpatient drug therapy often have less expensive inpatient hospital needs."

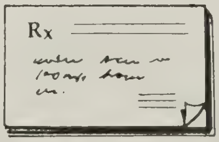
Sulfite Warning



Warning labels on prescription drugs containing sulfites may soon be required by the Federal government. Currently, sulfites are present in more than 1,100 prescription drugs, according to the Food and Drug Administration. However, most of these are IV solutions of antibiotics and local anesthetics; relatively few are oral products.

FDA has received more than 500 reports of possible sulfite sensitivity reactions, including 13 deaths, but these were due mainly to using sulfites as preservatives in fresh foods. In contrast, there have been only 14 reports of reactions from prescription drugs, and none from nonprescription drugs. The proposed labeling would state: "Contains (name of the particular sulfite), a sulfite that may cause serious allergic-type reactions [e.g., hives, itching, wheezing, anaphylaxis] in certain susceptible persons."

Prescription Drug Use



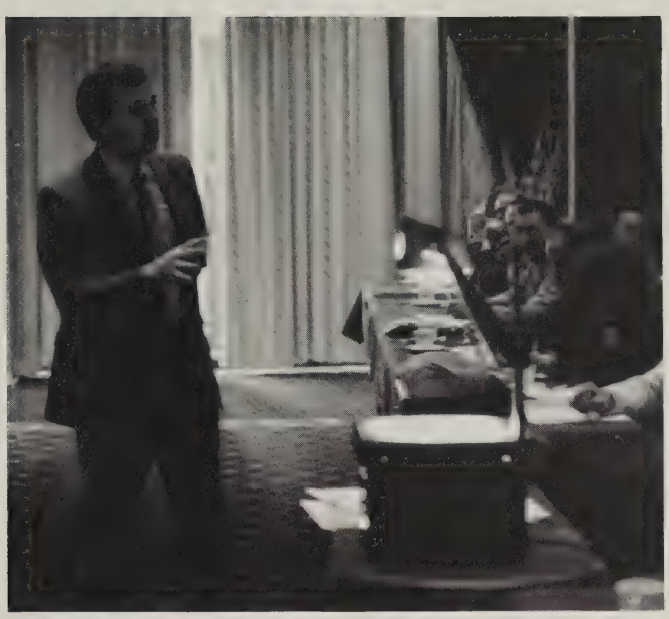
According to Food and Drug Administration figures released at the end of 1985, prescription drug use in 1984 equaled the previous 1973 high. In addition, half of the 1.5 billion prescriptions dispensed in 1984 were accounted for by five therapeutic classes: cardiovascular drugs (222 million), systemic antiinfectives (196 million), psychotherapeutic drugs (131 million—not including sedatives, which would add another 31 million), analgesics (116 million), and diuretics (110 million).

FDA said 71% of the cardiovascular drugs were used by people in their sixties or older, and women accounted for 54% of this use. About 89% of the prescriptions for the cardiovascular drug classes were in four drug categories: beta blockers, antihypertensives, vasodilators, and digitalis preparations. The FDA figures also show that diuretic use has increased over the past decade, from 78 million prescriptions in 1975 to 110 million in 1984. The use of thiazide diuretics has remained fairly constant, while prescriptions for potassium-sparing diuretics have more than doubled.

Provided as a service by the American Pharmaceutical Association.

APhA

Mid Year is "Best Ever"



Richard Wuest participated in the "Best Mid Year" ever at the Annapolis Hilton.

President Madeline Feinberg (left) and Thomas Gossel take a break. Gossel and Wuest presented an annual "Update on New drugs" as part of the Mid Year Meeting.

Warm temperatures and sunny skies were part of the attraction and led to this view of a sailing race in the Annapolis harbor during the Mid Year lunch break.

A record crowd turned out for the program. Continuing Education credits were available. The Hotel took extraordinary measures to accommodate the late registrants.

The Young Pharmacists Caucus met to discuss the programming for the Convention.

Grady Dale (left) presents the Pharmacy Achievement Scholarship to Lisa Ann Barbera. Philip J. Fiastro (right) was Lisa's sponsor for the Award. The ceremony took place during the Mid Year Luncheon.

POLITICAL ACTION

An Essential Commodity for Pharmacy's Future

Trent Lott, an influential member of Congress, recently told an audience of independent retail pharmacy leaders that "when I go back to my state, there are two stores that I go to in every town—one is the barber shop, the other is the local drugstore."

That's no accident. Smart politicians secure their future by knowing what's going on back home. And there's no better place to read the pulse of a community than the local drugstore.

"Localism is the great new force in American politics," noted political analyst Horace Busby recently observed. Retailers, more than any other group, are likely to shape the terms of the nation's future political debates, he maintained. "Your time is coming on the national stage—if you want it," he noted. That's a prophetic statement on the future of our pharmacy profession: The "national stage" *can* be ours—if we want it.

A PROFESSIONAL DUTY

But if we don't believe we are the masters of our fate, then we won't be. If we avoid skirmishes on marketplace issues because they seem somehow unprofessional, if we stand clear of the political trenches because they seem untidy, if we skirt, rather than accept, the political challenges before us, then we will have forfeited control of our profession's future.

No successful independent retail pharmacist lacks for either determination or self-confidence. There's no other way to approach the battle for such a hotly competitive marketplace. The political arena requires the same determination. Lee Iacocca didn't lift Chrysler up from the ashes—and back from default—by saying "we can't." He surrounded himself with a "can-do" team, stared down the future, and said, "we shall."

Pharmacy must adopt a similarly assertive attitude. Pharmacy's future will be won in the marketplace and in the political trenches. It will be shaped by the actions we take *today*.

MEETING THE CHALLENGE

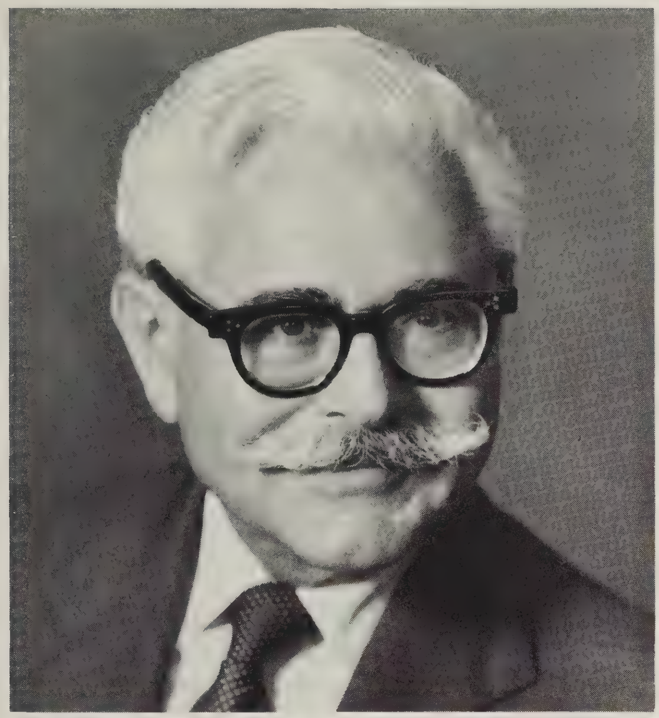
The recent victory over the feds in their attempt to confiscate pharmacists' earned discounts from the Medicaid program was a vivid demonstration of the power of political action. But that is just one of many formidable marketplace and political challenges pharmacy must address. To meet those challenges, we must acknowledge once and for all that politics and pharmacy are inseparable.

You may rest assured that our elected officials know that is so. They will always be there when they need you. It is our job to make sure they *always* do.

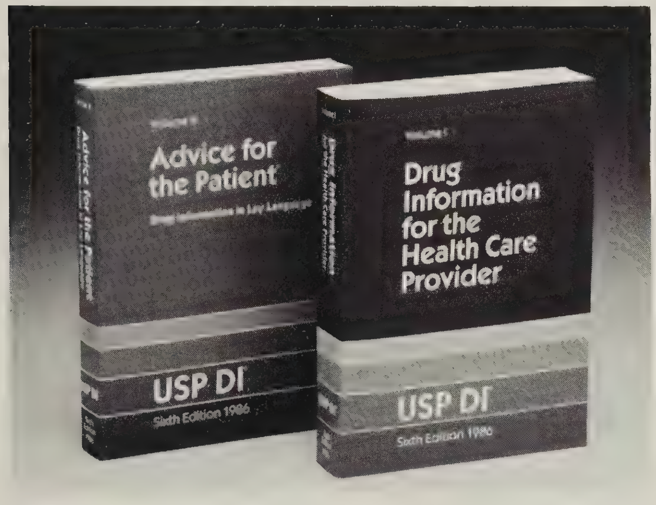
Many pharmacists are politically active at the local level, some lobby effectively at the state level, and a few are involved at the national level. One way to have a positive impact on the political process at all of those levels, however, is to contribute to your local or state PAC and to the National Association of Pharmacist's Political Action Committee (NAPPAC). When you contribute to a PAC, you are buying shares in a political mutual fund. Your dollars are invested in a wide variety of stocks for maximum yield—more clout than any individual could ever hope to achieve alone.

The strength of pharmacy lies in the participation of committed pharmacists—those who get involved in politics and stay involved. Our duty and responsibility is to leave pharmacy better than we found it. No less than the future of the profession we know and love is at stake.

FYI, a monthly perspective on topics of interest to pharmacists, is provided as a service by the National Association of Retail Druggists.



Jack Robbins from the Schering Corporation, presented the results of a consumer attitude survey at the Mid Year Meeting entitled: "What's Right With Pharmacy."


Advice for the Patient
USP DI
Sixth Edition 1986
Drug Information for the Health Care Provider
USP DI
Sixth Edition 1986

The newly revised and expanded 6th edition of the USP-DI are now available from the MPhA. Considered a landmark in drug information, it is a comprehensive drug data base for practicing pharmacists.

Edwards and Anthony Pharmacy received the Squibb's One Million Prescription Award. Pictured are (left to right) Ron Booze, Squibb; Stanley Protokowicz and George Voxakis, Pharmacy Owners and Jack Peters, Squibb. George is President of the BMPA and President-elect of the MPhA. Jack is the Past Honorary President of the BMPA.

Marlane S. Losh has been named District Manager of the Baltimore district for Syntex Laboratories. She will be responsible for all sales activity in the Baltimore area.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

METABOLIC ACIDOSIS: Several drugs can produce acidosis as a result of chronic administration. Two young people with normal renal function developed serious metabolic acidosis after having been given acetazolamide (Diamox) and salicylates. Acetazolamide is a carbonic anhydrase inhibitor which produces metabolic acidosis as a result of increased renal excretion of bicarbonate while salicylates are intrinsically acidic. *Br Med J,* Vol. 6441, #289, p. 347, 1984.

SHORT LEG SYNDROME: Since 1863, it has been known that it is not uncommon to find that a patient may have legs of unequal lengths. In a case controlled study conducted in Wales, investigators attempted to determine if a correlation could be made between unequal leg length and back pain. No association could be found to suggest that unequal leg length might be responsible for the production of back pain. *Lancet,* Vol. II, #8397, p. 256, 1984.

DETERGENTS: Animals given solutions containing detergents were found to develop gastrointestinal irritation and atrophic changes in portions of their tract presumably due to the emulsifying activity of these agents. Although this effect is not seen in humans because only low quantities of detergents are ingested, parents of small children are cautioned to rinse detergents from bottles and utensils used to feed the young. *Lancet,* Vol. II, #8399, p. 384, 1984.

METHYLATION AND MOOD: Many patients with psychiatric illnesses involving depression have been found to be deficient in folic acid and thus the methylation of various central nervous system transmitters is reduced because of the scarcity of this one-carbon carrier. Depression is a common symptom of folic acid deficiencies so investigators have postulated that adequate methylation processes are necessary to prevent depressive moods. S-adenosylmethionine, a substance also involved in methylation, has been used as an antidepressant with success in selected patients. *Lancet,* Vol. II, #8396, p. 196, 1984.

MUSCARINIC SUBTYPES: Muscarinic receptors are those activated by acetylcholine released from the post-ganglionic parasympathetic nervous system. Investigators have identified subtypes of these receptors and have named that M-1 and M-2 muscarinic receptors. The M-2 receptor is located in the central nervous system where it acts to inhibit acetylcholine release and in the periphery on smooth muscle of the bladder, bronchioles and ileum. In the stomach the M-1 receptor controls acid secretion and the M-2 regulates motility. Investigators will search for specific M-1 inhibitors to reduce gastric secretion without altering motility. *J Pharmacol Exp Ther,* Vol. 230, #2, p. 284, 1984.

FETAL RESPONSE TO EXERCISE: Maternal exercise requires an increased amount of oxygen and subsequently there is less available to the fetus. The fetus responds by developing a catecholamine-mediated bradycardia during the period of maternal exercise. Information gathered from studying women while exercising on a treadmill indicates that after the period of maternal exercise, there is a transitory increase in fetal heart rate to compensate for the slowing during exercise. *Lancet,* Vol. II, #8397, p. 258, 1984.

PHENYTOIN/BARBITURATE COMPARISON: Phenytoin (Dilantin) acts as an inhibitor of cellular excitability, thus making it useful as both an anticonvulsant and an antiarrhythmic agent. Studies conducted with isolated neurons suggest it produces its activity by acting to block sodium channels in neurons, thus reducing depolarization and excitability. This action is seen only when phenytoin is in the unionized state. In contrast, the barbiturates have been found to exert a similar effect on this *in-vitro* preparation but will block the channels when in either the unionized or ionized state. *J Pharmacol Exp Ther,* Vol. 230, #1, p. 156, 1984.

ETODOLAC: A new non-steroidal anti-inflammatory drug has been used in various doses to determine requirements needed for its maximal anti-inflammatory action. After having identified its potency as compared to ibuprofen (Motrin), indomethacin (Indocin), and naproxen (Naproxyn), a study relating to drug-induced gastric hemorrhage was initiated. Results show that etodolac (Ultradol) produced less gastrointestinal hemorrhage and irritation at maximally effective doses than did the other more conventional agents. *J Clin Pharmacol,* Vol. 24, #5, p. 240, 1984.

ISOTRETINOIN: Women taking isotretinoin (Accutane) during the early stages of pregnancy have been identified as being at risk of delivering infants with structural abnormalities. Efforts should be made to increase the awareness of this problem and women should be encouraged to discontinue therapy if they plan to become pregnant. A triad of symptoms may develop which include damage to the ear, heart and central nervous system. *Lancet,* Vol. II, #8392, p. 1465, 1984.

Patient Aid

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

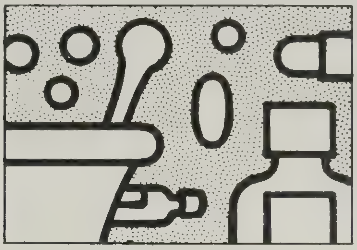
To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

state pharmaceutical
editorial association

There was a young girl named Medea
Whose hypochondria was quite severe
She took so many pills
For imaginary ills,
She was a human pharmacopoeia.

from: Morris Sackel
3710 Patterson Ave.
Baltimore MD 21207

Things You Should Know FOR YOUR GOOD HEALTH



Tips on Detecting Tampering

The first step in protecting yourself is an awareness that tampering, although probably very rare, may occur. It's up to you to apply some common sense. Here are some general suggestions:

Packages

- Are there bits of paper or glue on the rim of the container indicating there had once been a bottle seal?
- Are there breaks, cracks, or holes in the outer wrapping or protective cover or seal?
- Does the outer covering appear to have been disturbed, unwrapped, or replaced?
- Does a plastic band around the top of a bottle appear distorted or stretched, as though it had been rolled down and then put back into place? Is the seal missing? Has the band been split and retaped?
- Is the cap on an unsealed container tight? Is the bottle over-filled or under-filled?
- Are the instructions wrinkled, misplaced, or missing? Is the information and the lot number on the container the same as that on its outer wrapping or box?

Liquids

- Is it the usual color and viscosity? Normally clear liquids should not be cloudy.
- Liquids should not have particles in the bottom of the bottle or floating in the solution.
- Does it have a strange or different odor? Is the level in the bottle the same as other bottles on the shelf?
- All eye drops are required to be sealed at time of manufacturing to protect their sterility and indicate evidence of any opening.

Tablets

- Has their appearance changed: Is the color different? Do they have unusual spots? Are the tablets all the same size? Are they broken in pieces?
- Do the tablets have a strange or different odor or taste?
- If imprinted, do all the tablets have the same imprint? Is the imprint missing from some?

Capsules

- Are they cracked or dented? Are they of uniform size and color?
- Do they have their normal shiny appearance or are some dull or have fingerprints on them as though they have been handled?
- Do the capsule contents appear to be equally filled? Are the capsules all the same length?
- If imprinted, do they all have the same imprint? Is the imprint missing from some?
- Do they have an unexpected or unusual odor?

Keep in mind that not every change in the appearance or condition of a product means that the package has been tampered with. The manufacturer may have changed the color or the packaging of a medicine or it may have experienced rough handling in shipping. Some minor product variations may be normal.

Whenever you suspect anything to be out of the ordinary or unusual about a medicine or its packaging, have your pharmacist look at it. Pharmacists know what the usual appearance of the packaging and the product should be.

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The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Westview Mall Road Beltway Exit No. 15A. For further information contact President Frank Block (phone: 358-2743).

RX LICENSE PLATES

Again this year, the MPhA will be making available a special line of license plates from the Department of Motor Vehicles for Pharmacist members of MPhA. A special one time fee of $10.00 per vehicle will be required and should be added to the fees specified by DMV. Mail the total check and forms to MPhA for processing. The tags will have the "RXA" prefix and numbers will be given on a first come—first serve basis. Watch for further details.

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March 13, Thursday—Monthly MSHP meeting
March 15–20—APhA Convention, San Francisco
March 16–22—Poison Prevention Week
March 24–30—Pharmacy School Spring Vacation
April 6, Sunday—AZO Fritz Berman Pharmacy Seminar Meushaw's Hilltop Inn
May 2–3—Grass Root Seminar, Arlington, Va.
May 4–5—NIH Region Conference on High Blood Pressure Control
May 22, Thursday—Alumni Association Graduation Banquet
May 23, Friday—Commencement Exercises
June 20–22—MSHP Seminar, Ocean City
June 22–26—MPhA CONVENTION—SHERATON HOTEL, OCEAN CITY

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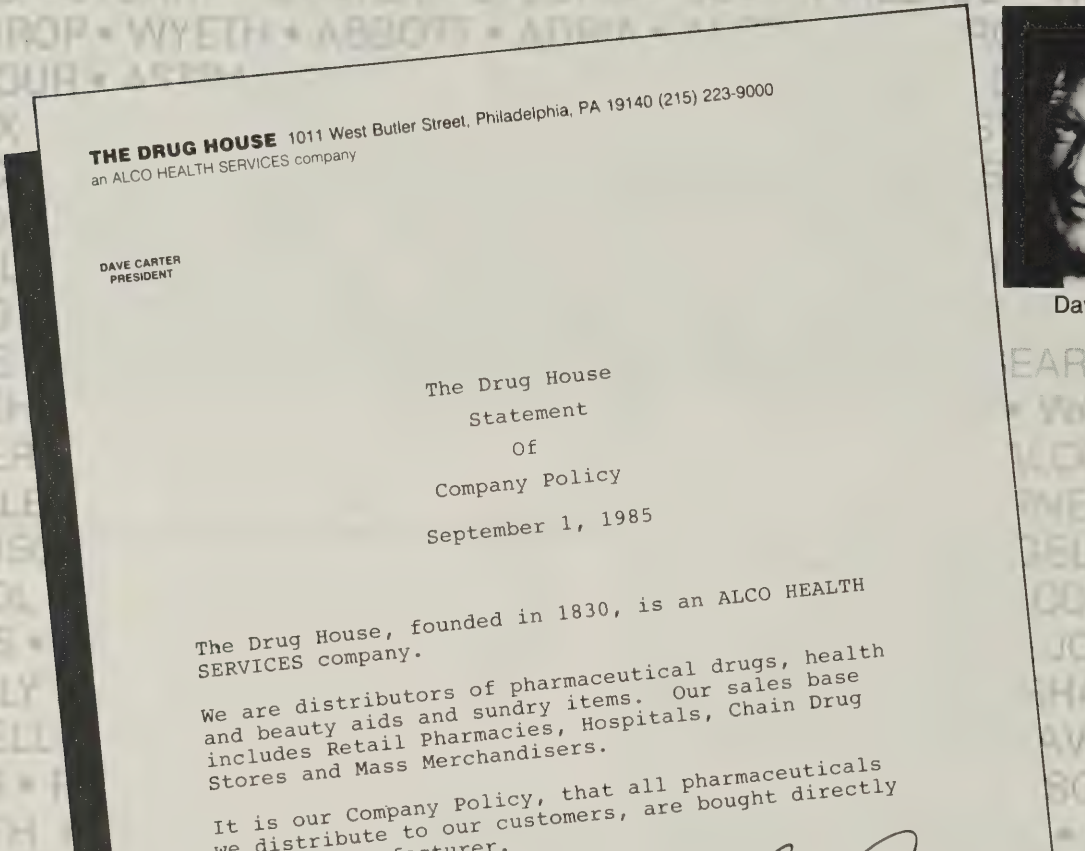

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DAVE CARTER
PRESIDENT

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Statement
Of
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September 1, 1985

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We are distributors of pharmaceutical drugs, health and beauty aids and sundry items. Our sales base includes Retail Pharmacies, Hospitals, Chain Drug Stores and Mass Merchandisers.

It is our Company Policy, that all pharmaceuticals we distribute to our customers, are bought directly from the manufacturer.

Sincerely,
Dave Carter
David C. Carter
President

David C. Carter,
President

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THE
MARYLAND
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Official Journal of
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April, 1986
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NO. 4

Advising Consumers on Soft Contact Lens Solutions

—J. Richard Wuest
—Thomas A. Gossel

Elder Ed Talk—Part II—The Aging Process

—Peter P. Lamy
—Madeline Feinberg

More on Reviewing Computer Contracts

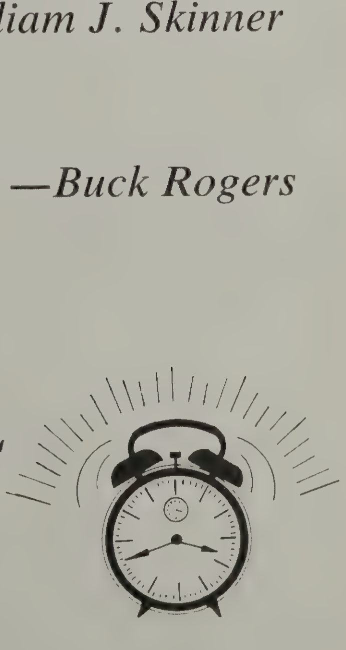
—William J. Skinner

The Pharmacy Space Soap Opera

—Buck Rogers

1986 Tax Dates

BEGINNING THIS ISSUE—SPECIAL FEATURE—"TIMELY TOPICS"



THE MARYLAND PHARMACIST

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President's Message

I didn't have time to write my own President's Message this month. Not because I'm playing hooky, but because I'm spending an exciting and challenging week at the APhA annual meeting in sunny San Francisco. Here's an example of some of the great lessons that I'll be bringing home.

Poli Sci 101 or
''HOW TO BE AN EFFECTIVE WITNESS''
(Adapted from Michael Sheehan, Associates Inc. Presented at the American Pharmaceutical Association Annual Meeting, San Francisco, ''First Impressions are Lasting: Skills of Lobbying and Testifying'' March 16, 1986.)

To be an effective witness:

—There is nothing to be afraid of.
—If you speak on behalf of a professional association, you will carry more weight.
—Effective testimony draws upon your real life experience. Give specific examples.
—Be brief, be honest and be specific.

You can make a difference:

—You are a private citizen, not a paid representative.
—You are a voter.
—You reflect the opinions of the ''folks back home''.
—You are an expert in your field. You are respected for your knowledge.

MPhA testified in Annapolis last month on two bills crucial to pharmacy practice in our state:

HB 1465	Regulating Mail Order Prescriptions
SB 830	Physician Dispensing

About ten pharmacists and one pharmacy student went to Annapolis to give their testimonies. They followed Michael Sheehan's guidelines and were very effective.

Madeline Feinberg,
PRESIDENT

The Maryland Pharmaceutical Association would like to honor our only 1985 *Sustaining Member,* **The Loewy Drug Co.** We sincerely appreciate their continued support.

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 3

Advising Consumers On Soft Contact Lens Solutions

by **J. Richard Wuest, R.Ph., Pharm.D.**
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, OH

Goals

The goals of this lesson are to:

1. discuss solutions and disinfection methods in the care of soft contact lenses;
2. explain how to advise patients on the proper use of the solutions.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. identify solutions intended for the care of soft contact lenses;
2. explain the proper techniques for using these solutions.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Contact lenses, including the basic differences between hard and soft lenses, and solutions used to care for hard contact lenses were discussed in previous lessons. A quick review of these topics will be helpful to better understand soft lens care products.

A basic but important difference between hard and soft contact lenses is that the soft variety is hydrophilic and will adsorb water. Most individuals who wear contact lenses report that the soft lenses feel more comfortable in the eye. However, soft lenses also have an affinity for adsorbing smoke, dust, protein, aerosol particles, bacteria, chemicals, and other foreign material. The more hydrated the lenses, the greater is their affinity for collecting deposits. They must, therefore, be thoroughly cleaned, and inserted and removed from the eyes properly.

The best technique for inserting and removing soft contact lenses is to first thoroughly wash the hands with a noncosmetic soap. The hands should then be dried with a lint-free towel. This is especially important for the fingers that will touch the lenses. The soft lens is then removed and cleaned.

Deposits that accumulate on lenses are the most bothersome aspect of caring for soft lenses. Improper cleaning is reported to be the most prevalent cause of eye irritation and injury, and is the leading reason why individuals discontinue wearing soft lenses.

An ideal method for cleaning soft lenses is to place two to three drops of cleaning solution on each lens surface, then gently rub the lens between the thumb and forefinger, or between a fingertip and the palm of the other hand, for twenty to thirty seconds. This emulsifies oily substances and loosens mucoproteins that have collected on the surfaces during wearing. The individual should use care to avoid scratching or cutting the lens with a fingernail because, unlike hard lenses, the soft variety can tear rather easily.

After cleaning, the lenses must be rinsed with sterile saline solution. Tap water should not be used because minerals in tap water can be adsorbed onto the lens. After they are thoroughly rinsed, the lenses must be disinfected by thermal or chemical means. Following this procedure, they are rinsed again with sterile saline solution and are ready to be reinserted into the eye, or they can be left soaking in saline solution for insertion later.

Cleaning Solutions

The ingredients in most soft contact cleaning solutions are basically the same as those in hard contact lens products. However, their concentrations in soft contact solutions are often lower.

There is a lack of objective comparative data for the various brands of solutions because few studies have been performed. Consumer preference and fitter recommendations determine which solutions within a particular category of soft lens products will be used.

Some manufacturers believe that high viscosity is important for cleaning solutions. Therefore, they include cellulose derivatives in their products to thicken them. Other manufacturers believe that solutions should be less viscous to assure optimal cleaning activity.

In either instance, thorough and complete rinsing of the lenses following use of any cleaning solution is extremely important to maximize removal of all of the chemicals and loosened debris. After cleaning, the individual should hold the lens up to a light. If the lens appears hazy or spotted, the cleaning procedure should be repeated.

There are two basic types of soft lens cleaning solutions, those intended for daily use and those for weekly use. Those just mentioned are used as **daily cleaners.** They consist of nonionic detergents and wetting agents, along with preservatives and buffers. These surface active solutions are effective for removing lipid accumulations. They are not as effective for protein deposits.

Cleaning solutions should be used immediately after removing the lenses from the eye. Once protein deposits accumulate on the lens surface, they become extremely difficult to remove.

Other cleaning aids are designed as **weekly cleaners.** They are used to supplement the surface-active cleaners. Milky white, opaque deposits can form on soft lenses. These deposits are composed of protein, a normal component of conjunctival secretions. They precipitate on the surface of the lens and become bound to the plastics. This then leads to decreased visual acuity, eye irritation, and the inability of the wearer to keep the lenses in as long.

Products for weekly use are available either as tablets to be dissolved in water, or as pre-mixed solutions of highly concentrated cleaning agents. The tablets contain papain or pancreatin which are proteolytic enzymes that destroy peptide bonds formed between the protein and the lens, without harming the lens. Lenses should be soaked in the solution for at least four hours, preferably overnight.

Individuals who use weekly cleaning solutions must follow the manufacturer's directions explicitly, including the rinsing off of all traces of the solution. If they fail to follow the directions correctly, the chemicals in the cleaners can adhere to the lens and later cause irritation to the eye as they are released after the lens is reinserted.

Rinsing Solution

The rinsing solution used for soft lenses is sterile saline. There are three basic types of products: preserved solutions, single-use unpreserved pre-mixed solutions, and solutions made from salt tablets.

First, the **already-prepared, preserved saline solution** is used by most soft contact lens wearers because of its convenience. Until recently, all commercially available preserved saline solutions contained thimerosal as the preservative. These solutions were basically interchangeable. However, thimerosal is an organic mercurial that interferes with bacterial cell metabolism, resulting in bacteriostatic action. It is reported to irritate the eyes in approximately 10 to 20 percent of those persons who use it. Individuals so affected can either use the **single-use, unpreserved premixed saline solution** which is more expensive, or prepare their own rinse from salt tablets.

Self-prepared saline solutions made from salt tablets have a cost advantage over commercially prepared products. But problems can occur if the individual does not prepare the solution correctly. Also, they must keep their storage bottle clean at all times.

Oral salt tablets intended to replace sodium which is lost in sweat during physical exercise should not be used to prepare solutions for rinsing contact lenses. These contain other ingredients, in addition to sodium chloride. Also, table salt should never be used to make saline solutions to rinse lenses because it contains iodine and numerous other impurities which can be irritating to the eye. Table salt is not required to meet rigid USP standards as sodium chloride intended for medicinal purposes.

Another common problem with preparing saline from salt tablets involves the use of bottled or tap water instead of distilled water. Again, these two types of water contain numerous impurities, some of which can ruin contact lenses. They can also be contaminated with bacteria and may contain particulate matter that is injurious to the eye.

Improper preparation of saline solutions may result in an incorrect pH. Changes in the pH can either shrink or expand the size of soft lenses. The same is true if the salt concentration is incorrect, resulting in a hypotonic or hypertonic solution.

The most important question is, "Has the solution been correctly prepared so that it is sterile?" If it isn't sterile, it should not be used to care for contact lenses that will be placed in the eye.

Recently, saline solutions preserved with sorbic acid have been made available in this country. These solutions, while more expensive than solutions self-prepared from salt tablets, are much less expensive than single-use containers of unpreserved saline solution.

Some manufacturers have recently introduced multiple-use, unpreserved saline solutions. If used correctly, these solutions will remain sterile for the few days during which the contents of a single bottle are used. In either instance, these solutions are usually better tolerated by individuals sensitive to thimerosal.

Disinfection Methods And Solutions

There are two basic methods for disinfecting soft lenses: chemical and thermal. Following cleaning and rinsing, soft lenses must be disinfected before being reinserted into the eye. The reason for this is that bacteria, viruses, fungi, and other microorganisms can be adsorbed onto soft contact lens surfaces, possibly resulting in infection.

The term *sterility* is not used because true sterility of soft lenses is not possible. As soon as the lenses are placed in the eye, they become recontaminated.

Figure 1 demonstrates a protocol for the various types of disinfection methods. There is some controversy as to which method is better, but many experts report that they consider **thermal disinfection** to be superior to various chemical means. Thermal disinfection is easier and causes less irritation to the eye.

The most common method for **chemical (cold) disinfection** is to immerse the lenses in a chemical disinfection solution for at least four hours in order to kill any adhering bacteria. There are solutions for both a two-step method (e.g., Normol/Flexsol and Soft Mate), and a one-step method (e.g., Flex Care and Bausch & Lomb Sterile Disinfecting Solution). Personal preference dictates which method a patient will choose.

Some experts believe that the two-step method is better for older patients and other persons with insufficient tear secretion because it adds another step to rinsing off chemicals that can irritate the eye.

A newer method of chemical disinfection utilizing hydrogen peroxide has recently been introduced to this country. It is widely used in Europe and has many proponents who claim better disinfectant activity and less eye irritation.

While the chemical method of disinfection is more expensive as far as purchasing the solution is concerned, it does not require electricity to perform. So, its higher initial cost is tempered somewhat by the fact that there is no additional expenditure for energy. Some experts feel that the chemical method is more likely to prolong the life of the lens. But others state that it is too irritating and that the thermal method is better.

Consumers should not switch from a chemical to heat disinfection method without seeking professional assistance. However, switching from thermal to chemical is possible. The reason for this is that switching from the chemical to thermal disinfection method without first leaching out all of the chemicals from the lens can render them opaque and useless. These chemicals can form hardened layers which may be baked into the lens surface by the heating process. Anyone choosing to make this transition must run the lenses through several soakings in fresh batches of saline solution.

Another method is to use the weekly enzyme tablet cleaner for several days, rinse the lenses in fresh saline six or more times the next day, then rinse again and sterilize. It may be best, however, to have the lens fitter purge the lenses using the special ultrasonic equipment in his office.

Chemical disinfection solutions must be completely rinsed off after each use. They contain thimerosal, and either chlorhexidine or hexadecyltriethanol ammonium chloride, all of which can cause irritation to the eye. They will bind to the lens, very little at first, but in increasing quantities as the lens ages.

Thimerosal does not bind with the lens matrix to the extent that it does with debris. Therefore, the cleaner the lens, the less chance for irritation.

Chlorhexidine and hexadecyltriethanol ammonium chloride, however, can bind tightly to lenses and accumulate in high concentration to soft lens polymers. If the lenses are clean, the chemicals are released very slowly and cause few problems. The presence of debris on the lenses enhances their release and, therefore, increases the chance for irritation.

There are also problems associated with **heat disinfection.** First, the storage case must be kept meticulously clean and should be scrubbed with surfactant cleaners at least once a week. It should then be rinsed with hot tap water and rinsed with saline. The individual should make sure his storage case doesn't leak. If it does, the solution can evaporate during heating and the lens may be ruined.

The heating unit must also be checked regularly. The rubber gaskets may deteriorate because of repeated heating. This could result in evaporation during heating, with th lenses sticking to the unit, thu damaging them. The unit itself ma not heat sufficiently so that the lenses are improperly disinfected Othertimes, the unit may fail to shu off.

At one time, heating units sterilized soft lenses by essentially th same mechanism as autoclaving, i.e heating to 220°F or higher and holding the temperature for twenty minutes or longer. One problem wit this method was that daily boilin severely shortened the life of th lenses. The newer heating unit merely raise the temperature t about 175°F and maintain it for approximately ten minutes. This procedure has the same effectiveness a boiling because it is done unde pressure. The complete cycle fo heat disinfection generally require from twenty to thirty minutes. Afte cooling, the lenses can be remove from the heating unit and inserted.

The individual should not reus preserved saline in a heating unit This can lead to grey discoloratio due to thimerosal precipitation o the lens. He should never use chemical disinfectant solutions for th thermal procedure because, again chemicals in those solutions can adhere to and ruin soft lenses.

Tables 1 and 2 contain a summar of representative contact lens solutions and their ingredients. One ca readily see that there is a similarit between various solutions withi the same categories. Aside from personal bias, many experts believ that, within a group, the products ar basically interchangeable.

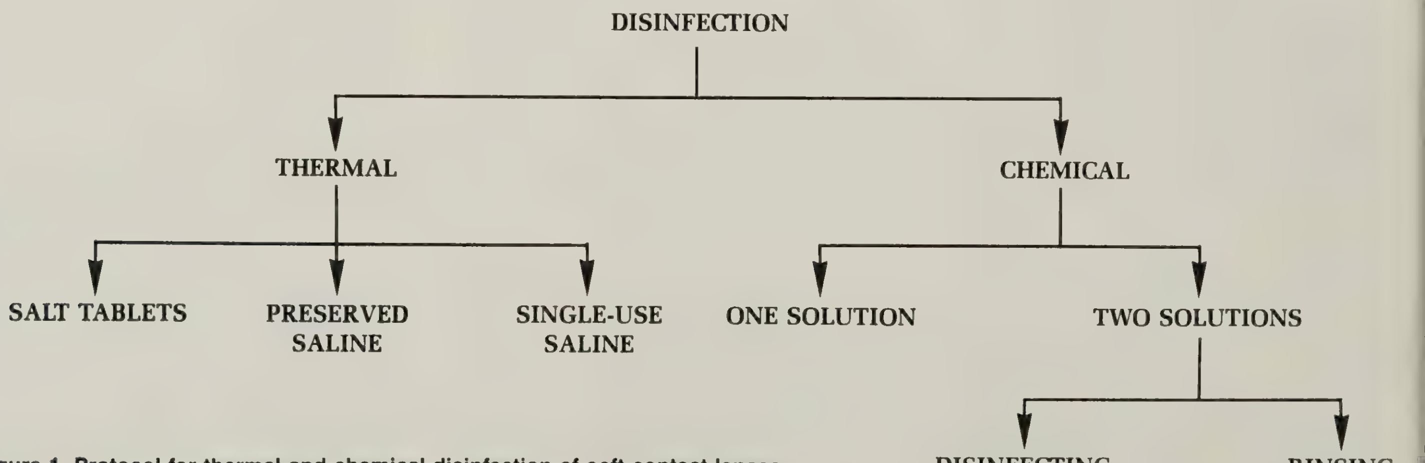


Figure 1. Protocol for thermal and chemical disinfection of soft contact lenses.

TABLE 1

Ingredients in Contact Lens Solutions and Their Functions

CHELATING AGENT:
- Ethylenediamine tetraacetic acid (EDTA)*

DETERGENTS:
- Octylphenoxyethanol (OCT)
- Tyloxapol (TYL)

DISINFECTANTS:
- Chlorhexidine (CH)
- Hydrogen peroxide (H_2O_2)

PRESERVATIVES:
- Potassium sorbate (PS)
- Sorbic acid (SA)
- Thimerosal (TH)

SURFACTANTS:
- Bis-2-hydroxyethyl tallow ammonium chloride (BTA)
- Polysorbate (Polyoxyethylene) 21 (P21); 80 (P80)
- Poloxamer 407 (P407); 188 (P188)
- Polyvinyl alcohol (PVA)
- Povidone (Polyvinylpyrolidine) (PPP)
- Tris-2-hydroxyethyl tallow ammonium chloride (TTA)

VISCOSITY AGENTS:
- Hydroxyethylcellulose (HEC)
- Polyvinyl alcohol (PVA)
- Propylene glycol (PRG)

*The abbreviations within parentheses are to simplify Table 2. They are not the chemical formulae for the compounds listed.

Common Consumer Questions

There are several questions that are asked by contact lens wearers regardless of the type of lens worn. Some questions and suggested answers follow.

"My vision is foggy. What should I do?" The individual should clean the lenses again. If vision is still impaired, the person should make sure the lenses are in the correct eyes. If the problem is still not corrected, a physician should be contacted. It is possible that he is experiencing corneal hypoxia (insufficient oxygen to the cornea). The same advice is appropriate if the individual sees halos around lights, especially at night.

"I fell asleep with my contacts in. What should I do?" This is not a problem if the lenses are the soft variety. With hard lenses, however, it can be quite an unpleasant and memorable experience.

The first thing the person should do is blink the eyes often and hard, to try to increase tear secretion. Next, he should flush the eyes with a large quantity of saline, possibly by placing several drops into the eyes. He should continue blinking, and, after cleaning the hands thoroughly, try to remove the lenses. If they can't be removed or if severe pain is noted, the person should immediately go to the fitter's office or to an emergency medical service. These facilities have specially-made suction cup devices which can be used to remove the lenses.

TABLE 2

Commercially Available Soft Contact Lens Solutions

CLEANING (Daily)	**INGREDIENTS***
Daily Cleaner (B&L)	PVA, TYL, HEC, TH, EDTA
LC-65	?, TH, EDTA
Pliagel	P407, SA, EDTA
Preflex	Same as B&L
Soft Mate Daily	OCT, HEC, TH, EDTA
Soft Mate ps Daily	OCT, HEC, PS, EDTA
CLEANING (Weekly)	
Alcon	Pancreatin
Softlens	Papain
Soft Mate	?, TH, EDTA
DISINFECTING	
Allergan	BTA, TTA, TH, PRG, P80
B&L Disinfecting	CH, TH, EDTA
Flex Care	Same as B&L
Flexsol/Normol	CH, PPP, P80, TH, EDTA
Septicon	H_2O_2, Na´stannate, Na nitrate
Soft Care	CH, PPP, OCT, TH, EDTA
Soft Mate Disinfecting	Same as Soft Care
Soft Mate Rinsing	CH, TH, EDTA
All contain NaCl and a borate buffer	
PRESERVED SALINE (NaCl +)	
B&L	TH, EDTA
Boil 'N Soak	Same as B&L Preserved Saline
Hydrocare	TH, EDTA
Lensrins	TH, EDTA
MiraSol	P407, TH, EDTA, SA
Sensitive Eye Saline	SA, EDTA
Soft Lens Rinse	TH, EDTA
Soft Mate Therm	Same as Soft Lens
Soft Mate ps	PS, EDTA
Sorbi-Care	SA, EDTA
LUBRICATING	
Adapettes	PPP, TH, EDTA
B&L Lubricant	PPP, TH, EDTA
Clerz 2	HEC, P407, SA, EDTA
Lens-Wet	PVA, TH, EDTA
Soft Mate Comfort Drops	PVA, HEC, TH, EDTA
Soft Mate ps Comfort Drops	PVA, HEC, PS, EDTA

*See Table 1 for explanation of ingredients.
? = contains unidentified ingredient(s)

"My eyes hurt when I wear my lenses. What should I do?" First of all, the individual should remove the lenses. If the pain subsides, the lenses should be cleaned and rinsed, and replaced in the eye. If the pain continues, the lenses should again be removed and examined against a light to see if there is anything unusual on them. If not, they should be rinsed again and reinserted. If the eye still hurts, the individual should see the fitter or a physician, or repeat the entire process again.

If pain continues after the lenses are removed, a physician should be consulted. The potential for corneal abrasion is significant. This is not amenable to self-treatment.

"Can I switch brands of contact lens solution?" The answer is probably yes, if it is the same type of solution for the same type of lens. The answer is absolutely no, if the label does not specifically state that the solution is intended for the type of lens being worn. Since contact lens solutions are included under the "Device" section of the Pure Food, Drug and Cosmetic Act, they must be tested for safe use for each specific type of lens. Solutions for hard lenses are not indicated for use with soft lenses. They are generally highly concentrated and their ingredients (most specifically benzalkonium chloride) may damage the lenses or injure the eyes.

"Can I switch from a chemical to thermal disinfection system?" It is in the individual's best interest to call the fitter before attempting this transition, to assure that all of the chemicals are leached out of the lenses before they are heated.

"Can I use tap water to dissolve my enzyme tablets?" The answer, absolutely not! These tablets must be dissolved in either distilled water or saline depending on the product. Tap water can inactivate the enzymes.

"How about using tap water for preparing my saline from salt tablets. Is this okay?" Again, the answer is absolutely no.

Summary

General consumer advice for contact lenses and their solutions was summarized in last month's lesson.

Wearing contact lenses and using contact lens solutions is relatively safe, and not associated with difficult procedures or dangerous problems. It should be kept in mind that contact lenses are foreign substances that are placed in the eye. The person's present and future vision is at stake. Common sense and good professional judgement should be paramount in any consumer advice on the use of eye preparations.

Because soft contact lenses are hydrophilic, they can readily react with environmental chemicals, cosmetics, and drug products used in and around the eyes. They must be sterilized (disinfected) before reinsertion to reduce the chance for contamination. The pharmacist should assure that these points are understood.

Contact lens wearers should comply with all steps involved in caring for their lenses. Pharmacists should assure that all solutions are stocked at all times. Consumers should be reminded to keep an adequate supply at home, including back-up containers.

Contact lens wearers usually start out with the best intentions for keeping their lenses clean and properly cared for. However, over time, they may become less concerned with protocol. While some persons can afford to be less concerned because their tear secretions contain few proteins and accumulated deposits on their lenses are not excessive, others may experience significant build-up. Individuals should be reminded to properly care for their lenses. This will be made easier if the pharmacist is available to counsel lens wearers on the proper use of the products he provides.

LETTERS

Dear Mr. Banta:

It has come to my attention that in the "Maryland Pharmacist" of January, 1986, Volume 62, Number 1, Page 29, reference is made in an article pertaining to Quinaglute Dura-Tabs by Berlex Laboratories and the generic equivalent manufactured by Bolar Pharmaceutical Company. The title of the article is "Quinidine Gluconate".

Since I am certain your publication strives for accuracy and fairness, I feel that you should be aware of the following information concerning the study by Berlex Laboratories upon which its data was based:

The exact title of the article in "Clinical Therapeutics" was "Bioavailability of Two Manufacturers' Sustained Release Quinidine Gluconate Tablets at Steady State". The study report was written by Miguel A. Zinny and William V. Taggart.

The Berlex study showed differences between the Bolar and Berlex products insofar as pharmacokinetic data and performance was concerned at *steady state.*

It is important to note that this Berlex study generated data from subjects who were supposedly in a steady state condition. However, examination of the subjects who were at "steady state" revealed:

"The study was to be done as a multiple dose, steady state study. Examination of the Cmin plasma levels of the day preceeding the steady state study reveals that only 62% of the subjects were actually at steady state during the 12 hour period immediately preceeding the study dosing interval. For the 12 hour period one day prior to the study, only 43% and 62% for period I and II respectively, were at steady state. As a result, the Cmin and Cmax values calculated for the steady state period are not true maximum and minimum values."

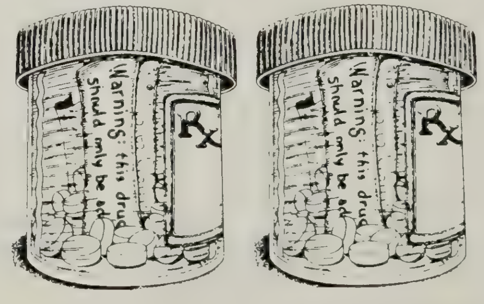
"Examination of this data for each subject during each phase of the study shows widely fluctuating plasma levels, with multiple peaks for more than 50% of the subjects. In addition, in some cases the time at which the Cmax and Tmax was determined was just the highest of the multiple peaks, which is not necessarily the true Cmax."

Obviously, this study has so many flaws, questions must be raised as to its validity.

The above information, including the calculations, have been verified by the FDA.

I feel certain you will take whatever steps necessary to present the true picture concerning the above study since it was printed in your publication.

Sincerely,
Seymour Inkles
Director
Scientific Affairs
Bolar Pharmaceutical Co. Inc.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Continued from March

II. Elder-Ed Talk: The Aging Process and How It May Affect Your Response to a Medication

The aging process—and how it may affect the older adult's response to medications—is the second in a series of programs suggested for presentation to community groups. The programs being outlined in this series have been the most popular of Elder-Ed talks and are now being updated and reprinted on a monthly basis for the next several months. We encourage pharmacists to detach these pages which can serve as a handy "script" for those called upon by community groups to speak on issues of medications. Not only elderly groups, but their caregivers (family, friends, other health care professionals) are reaching out to the pharmacist for his/her expertise in drug therapy management. We strongly encourage pharmacists to respond to these community requests and we offer these outlines to support the pharmacist in meeting these requests. Pamphlets which accompany these presentations are available through the Elder-Health Office, 20 North Pine Street, Baltimore 21201, (301) 528-3243. Thanks to the support of the Parke-Davis Company, these pamphlets are available in bulk quantity for distribution to elderly at community programs or in the pharmacy.

* * * * * *

The aging process is marked by great variability in process and consequences. People grow old at different rates and at different ages, and variability increases with increasing age. Some of the differences observed in aging can be attributed to genetic factors, some to environmental factors. Most important for elderly and their caregivers to understand is that certain factors which accompany aging may affect the way medications act in the body. Therefore by understanding some of the more important processes involved in drug action, individuals may be able to optimize the benefit of medications. We need to teach techniques of self-observation. We need to emphasize the elderly's responsibility to report these observations. We need to teach good "consumerism", that elderly must demand that questions and concerns regarding medication therapy be addressed by all providers.

The subject matter of this second talk follows the pill as it is swallowed and travels through the body. Factors involved in simply swallowing medications, factors which influence absorption are among those which can readily be controlled by the patient himself. We explain briefly the dynamics of drug distribution, metabolism and elimination to increase the patient's understanding of the processes which can be affected by age, disease, other medications. We hope that through this understanding, the patient will feel more disposed to questioning and sharing their experience to enable us, as providers, to assist in optimizing drug therapy.

Madeline Feinberg,
Director Elder-Health Program

THE AGING PROCESS: AND HOW IT CAN AFFECT YOUR RESPONSE TO MEDICATIONS

HOW TO KNOW YOU'RE GETTING OLDER . . .

Everything hurts, and what doesn't hurt doesn't work
The gleam in your eye is from the sun hitting your bifocals
You feel like the morning after, and you haven't been anywhere
Your little black book contains names only ending in M.D.
Your children begin to look middle aged
You finally reach the top of the ladder, and find it's leaning against the wrong wall
Your mind makes contracts your body can't keep
A dripping faucet causes an uncontrollable bladder urge
You look forward to a dull evening
Your favorite part of the newspaper is "20 Years Ago Today"
You turn out the lights for economic reasons, rather than romantic reasons
You sit in the rocking chair and can't get it going

Your knees buckle and your belt won't
You regret all those mistakes you made resisting temptation
You're 17 around the neck, 42 around the waist, and 96 around the golf course
Your back goes out more than you do
A fortune teller offers to read your face
Your pacemaker makes the garage door open when you see a pretty girl
The little old gray haired lady you help across the street is your wife
You sink your teeth into a steak and they stay there
You have too much room in the house and not enough in the medicine cabinet
You know all the answers but nobody asks the questions

I. Introduction

1. Introduce yourself and tell about the program
2. Aging: a normal process, not a disease process
   a process of change
3. How we change:
   —do we still run 3 blocks to catch a bus?
   —do we eat like we did when we were 20?
   —do we sleep 8 hours a night as we did in our youth?
4. These normal changes may also affect the way medications act in our bodies:
   —elderly may react differently
   —pediatrics has become a specialized branch of medicine
   —with increase knowledge about the elderly, geriatrics may also become a recognized specialty
5. Why are the elderly at greater risk: THIS WILL BE DISCUSSED AS WE FOLLOW A MEDICATION ON ITS TRIP THROUGH THE BODY.

II. A trip through the body:

Purpose:

To make you aware of what is happening when you take a medication

To help you avoid some unnecessary side effects

To help you determine if you may be experiencing side effects and what you should do about it

III. Swallowing the tablet:

1. Difficulty in swallowing
   —due to dry mouth (normal in older persons, or may be caused by other medications, e.g. antidepressants, antispasmodics, etc.)
   —how to deal with this problem:
   crushing tablets (check with pharmacists. Some must not be crushed)
   opening capsules (newer capsules may be sealed, check with pharmacist)
2. Dentures—may interfere with chewable tablets and can be irritating

IV. Absorption—tablet goes to stomach where it begins to dissolve so that it can be absorbed into blood stream

(some medications, e.g., antacids, are not absorbed, but work in stomach; laxatives are not absorbed but work in small and/or large intestine.)

1. Avoiding stomach upset (one of the major side effects of medication)
   —take with plenty of liquids (check with pharmacist which liquids cannot be taken with medication)
   —adequate liquids are IMPORTANT in general. Elderly tend to become dehydrated (often, they do not feel thirst and forget to drink; or they may avoid fluids)
   —discuss what "take on an empty stomach" means
   —discuss why some medications should be taken with food or milk
   —discuss why some products are buffered (e.g., helps aspirin to dissolve more quickly)
   —discuss why some products are coated (e.g., Ecotrin®) and how this affects drug action (e.g. delayed therapeutic effect)

V. Distribution of active ingredient to tissues of body

Once medication is absorbed into blood stream, it is carried to all tissues of body

Factors which determine medication distribution to body tissues:

—Cardiovascular function: may be diminished in older people. Therefore, may take longer for medication effect
—Changes in body composition with aging: as we age, there is likely to be a decrease in muscle tissue and an increase in "fatty" tissue. This can affect how the drug is stored in the body and how well the medication will work.
—Other medications may affect process (e.g. protein binding)

VI. Blood Levels: (therapeutic and toxic levels)

In order for a medication to work, you need to have a certain amount of drug present in the body. Think of a sink:

In order to get the sink half full, you need to add a certain amount of water. If the drain is open, we need to add enough water to fill the sink as it empties from the drain. On the other hand, if the drain does not empty well, water builds up and the sink overflows.

Think of the body as a sink. Think of the drug as the water going in. When the drug does not get out of the body as fast as you put it in, you begin to see more side effects (or toxicities) of the medication.

Other factors may also be involved in how fast the drug is absorbed into the body, then eliminated. Cardiovascular function, the presence of other diseases, diet and nutrition, exercise and activity levels and also whether or not you are taking other medications at the same time can affect this process.

VII. Metabolism

The drain of the sink is the liver and kidney, which are the two major body organs that eliminate drugs. These organs metabolize or eliminate the drug substance.

The liver performs over 5000 chemical reactions. Chemical change usually makes the drug more water soluble so that it can be eliminated. In some instances, the water soluble metabolite is inactive (will not have a drug effect in the body), but in other instances, the metabolite will also be active. Then the drug action may last longer (and you do not have to take as many doses to get the effect of the drug.)

The kidney eliminates many medications from the body in the urine. If kidney function is significantly slower, this may affect how quickly the drug is eliminated

VIII. Questions you should be asking to determine whether your medication is having the desired effect:

1. Questions to ask the doctor
    - —How can I expect to feel when I begin taking this medication?
    - —What is it for, and how long will I have to take it?
    - —Can I expect any side effects?
    - —What special precautions should I take when I use this medicine?

   Some common side effects of medications (ask audience to participate)

   tiredness
   dizziness
   constipation
   upset stomach
   sleep-changes
   diarrhea & incontinence
   blurred vision
   mood changes
   rashes
2. What should you do if you suspect the drug is not working right?
   The pharmacist is the medication expert. He can tell you if the problem is serious and can suggest solutions.

IX. Conclusion:

The purpose of a drug: it is not to adversely affect a patient's physical, physiological, mental, nutritional and health status. Most importantly, drugs should not diminish a patient's already diminished quality of life.

REMEMBER: Drug response of the elderly is much more unpredictable than it is in younger persons.
Always expect the unexpected.
Ask questions. Demand answers.

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“Timely Topics”

Beginning with this issue of *The Maryland Pharmacist,* the Parke-Davis Center for the Education of the Elderly, University of Maryland School of Pharmacy, will sponsor a monthly column addressing ‘‘what's new’’ on issues of disease management in the elderly. At the conclusion of each topic, a sample Elder-Ed talk on the subject covered will be outlined and can be added to the repertoire of community programs which are most frequently requested by older audiences. The first topic to be covered over the next several issues is osteoporosis. After all, who has not heard the question ‘‘Do I need to take calcium?’’ ‘‘How do I know if I have osetoporosis?’’

Osteoporosis: The Silent Epidemic

Part I. Definitions, epidemiology, pathophysiology

Osteoporosis is recognized as a major public health problem. It affects up to 20 million Americans and is responsible for more than one million fractures a year in persons over 45 years of age, with 75% of these fractures occurring in those over 65 years. The annual costs of this disease approaches $4 Billion. Even more devastating than costs are the incidence of morbidity and mortality associated with the disease. The complication rate for hip fractures within the first year following injury may be as high as 20%. It is estimated that 10% of those suffering from hip fractures die within three months. Fifty percent of elderly women who sustain a fracture of the hip do not regain their independence.

Definitions: Osteoporosis is an age-related disorder characterized by decreased bone mass and increased susceptibility to fracture. Primary osteoporosis is classified as either senile (age-related) or postmenopausal, a distinction which is important in terms of treatment and prevention.

Secondary osteoporosis is the same abnormality, but its cause can be attributed to factors which may include malabsorption syndromes, drugs which interfere with calcium absorption or regulatory mechanisms controlling bone growth, endocrine disorders, renal problems or immobility, among other factors.

Epidemiology: Although primary osteoporosis is an age-related alteration of normal bone function, there are certain population groups which are at greatest risk. Postmenopausal white women are most susceptible. Whites, in general, are more likely to have the disease than blacks. Women are at much greater risk than men. Certainly many postmenopausal women will not develop the disease, but it appears that by age 65, 25% of all women may suffer from osteoporosis. All people, men and women, do lose bone mass as they age. The process occurs more slowly in men.

Pathophysiology: Osteoporosis typically involves the hip, spine and wrist although all bones may be involved. Bone is constantly being broken down and built up, a turnover that is mediated by osteoclasts and osteoblasts. The process is regulated by mechanical, electrical, hormonal and local controls. At the cellular level osteoporosis occurs when the osteoclast activity (breakdown) exceeds the osteoblast activity (buildup). Estrogen plays a key role but exact mechanisms remain unclear.

There are two major forms of bone, cortical and trabecular. Differences in turnover rate and differences in individual patients yield subgroups of patients who are at risk to different types of fractures.

Bone loss is most rapid following menopause. It may be as great as 2% of total bone mass per year. The rate of loss declines with time but is most dramatic when there is a sudden decline in estrogen levels. Women who undergo early menopause will therefore be at greatest risk to development of the disease unless preventive measures are taken.

Individuals who are small-boned are intrinsically more susceptible to the disease. So too are those with less body fat. Following menopause, conversion of the sterol andostenedione to estradiol occurs in muscle and fat and becomes the main source of estrogen. This may explain why thin women are at greater risk.

Simple mechanics also explains why risk for fractures increases with age. In addition to decrease in bone, muscle mass may be inadequate to absorb stress which may then precipitate a fracture.

Inadequate calcium intake is strongly implicated in osteoporosis. More than ⅔ of the adult population do not meet the recommended daily allowance (RDA) for calcium. And the RDA for calcium has been found to be too low to prevent net bone loss in the adult. Although the RDA for calcium is 800 mg per day, most studies recommend 1,000 mg per day for adult women prior to menopause, and 1,500 mg per day following menopause.

Problems of inadequate calcium intake are amplified by alcohol consumption which both decreases calcium absorption and increases plasma cortisol which impairs normal bone growth. So too, caffeine and nicotine impair calcium absorption. High protein diets increase renal elimination of calcium. These factors must be considered when evaluating patients for risk to the disease.

Adequate Vitamin D is also required for most effective utilization of calcium by the body. Patients in nursing homes and others who remain indoors may require supplementation if dietary sources are inadequate.

Exercise, or lack of it, is strongly implicated in the development of osteoporosis. It appears that the osteoblast is stimulated by mechanical signals which stimulates production of prostaglandin E_2. This in turn appears to stimulate production of DNA in the osteoblast. It has been shown that electrical signals stimulate DNA synthesis in the osteoblast as well. (In fact electric current has been used to promote healing of certain types of fractures.)

Many factors then are implicated in the development of the disease. Pharmacists need to recognize that all patients over the age of 35 may present with some of these risk factors. It would be inappropriate to limit our concerns to just "little old ladies". A significant proportion of our patients may be, or are potential victims.

* * * *

The next several articles will discuss diagnosis, treatment and prevention of osteoporosis.

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MPhA Lobby Fund Contributors

Part II

The following pharmacists have contributed to the MPhA Lobby Fund as of press time. The Association has retained Mr. Judson Garrett as a professional legislative representative to assist in the 1986 Lobby effort. The three main issues which the Legislative Committee have identified for action are: regulation of Dispensing Physicians, regulation of mail order prescriptions, and immunity for the Rehabilitation Committee. These issues affect every Maryland Pharmacist! *It's Not Too Late* to join this list. The Lobby Fund Raising effort does not stop now. We will continue to publish the names of those concerned pharmacists who contribute to this special fund raising effort. Send in your check to the MPhA office for $20.00 or more. Lobbying for Pharmacists is expensive. Help us Hang in There for you.

Robert Beyer
James Edwards
Gary L. Haas
William C. Hill
Lenoard Jarkowski, Jr. Empire Pharmacy
Dale Klemm
A. D. (Bud) LaChappelle
Mark Levi
Robert Martin
Michael Roberts
Phillip Marsiglia
Oscar Scharpio
Norma Scharpio
Richard L. Walsh

More on Reviewing Pharmacy Computer Contracts

by William J. Skinner, Esq., P.D.

In 1983 we reviewed contracts of eight pharmacy computer suppliers in a speech and article for *The Maryland Pharmacist*. This article is an update on two additional pharmacy computer systems. Since 1983 Giant Pharmacies and other chains have advertised the addition of computers to their Maryland pharmacies. Software programs are getting easier to operate and will do more functions for less initial cost. It is time for you to look at pharmacy computers again.

There were twelve points covered in my 1983 article that are important for pharmacists to review when they are considering buying a computer system for the pharmacy. They are still important. These points are:

1. ''Merger'' clause and parole evidence rule
2. Warranty disclaimer/fraudulent misrepresentations
3. Limitations on remedies
4. Governing law clause
5. Delivery
6. Acceptance
7. Payments
8. Taxes
9. Maintenance/reliability
10. Software and software documentation
11. Confidential proprietary information (licenses)
12. Disclaimers, specifically related to professional practice

QS/1 Data Systems and Compute-Rx Management System were both demonstrated at the 1985 Annual Meeting of Maryland Pharmacists' Association. Both also submitted to the author copies of their contracts currently in use with the sale of their systems.

QS/1 Data Systems uses a contract form, written as a license agreement, which refers to exhibits that amount to a purchase contract and a separate service agreement.

Compute-Rx uses a printed two page purchase agreement and a separate four page service agreement. The latter refers to licenses but is a general agreement and not written as a license agreement.

I will make a few brief comments about each one of the twelve points that I have listed, and add additional information but I must advise that every contract has to be read in its entirety. Read it carefully, and understand the contract before you sign it. If you do not understand it consult an attorney to find out what it means.

1. *"Merger" clause and parole evidence rule*

Both contracts contain, in capital letters, an acknowledgment that the contract is the exclusive agreement between the parties. With this kind of clause there is no way you are going to be able to make the comments of a salesman a part of the contract. Remember, it must be in writing and the contract says it must be in a certain kind of writing to be a part of the contract.

2. *Warranty disclaimer/fraudulent misrepresentations*

QS/1 has a definite warranty that the system will conform to specifications. It has a further limitation of liability in that the previously stated warranty is the only warranty that is given. A warranty that a product will meet specifications is not a warranty that it will operate the way it should. The law of Maryland and other states usually have something to say about how limited warranties can be made in a contract.

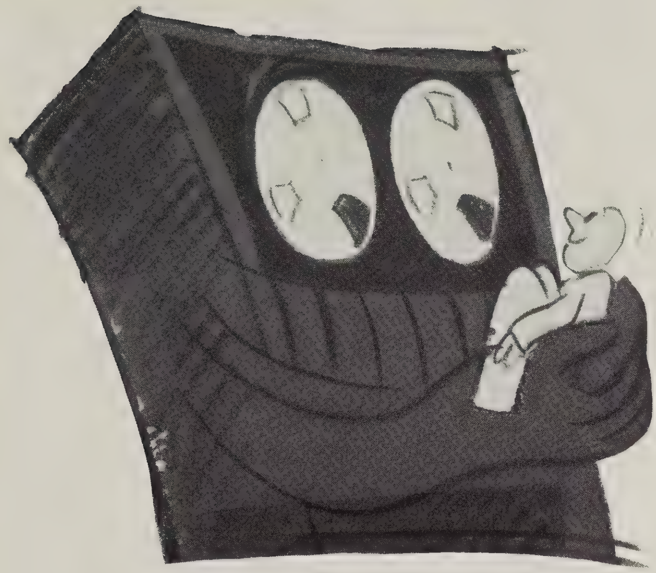
Compute-Rx also has a limited warranty in that the company promises to use its best efforts to provide any required maintenance and for failure to do so an amount equal to one month's service charge will be refunded. Parts, components and modules are warranted against defects and workmanship and material for a one year period after installation. There are further specific limits to the warranties and damages in the contract.

3. *Limitations on remedies*

QS/1 says its liability for damages is limited to a maximum of $10,000 and this applies to personal injury and damage to property caused by the negligence of the company. Further, QS/1 will not be liable for loss of profits, lost savings or other incidental or consequential damages even if they are advised about the possibility of the same. Compute-Rx, on the other hand says that its liability is limited to that one month's service charge.

Under Maryland law, warranties can be expressed by affirmation, promise or description or even by samples. Section 2-313 Commercial Law Code. An implied warranty of merchantability may arise from the course of dealing or the usage of the trade and may be specifically excluded or modified. Sections 2-314 and 2-316 Maryland Commercial Law Code.

Thus, it is important to see what is excluded or lim-



A COMPUTER CAN BE A PHARMACISTS BEST FRIEND !

ited in the warranties. Normally, these things would be in all capital letters, bold print or underlined to call your attention to it. When it is written that way, be sure to read it.

QS/1 says that no remedy can be brought by either party more than two years after the cause of action arises, or if it is for non payment, for more than two years from the date of the last payment was due.

Compute-Rx on the other hand will not recognize a breach of an agreement unless it is brought within one year after the cause of action has accrued or less than two years after the date of delivery of the product referred to, which ever occurs first.

These are definite limitations on the Maryland law which gives the Statute of Limitations as three years either in contract or tort actions.

4. *Governing law clause*

In the QS/1 Agreement the Law is governed by the State of South Carolina. The Comput-Rx contract is governed by the Laws of Virginia. While most states' uniform commercial code are similar to the Maryland Commercial Law Code, there are differences from state to state. Therefore, if you have any questions about the specific application of the Commercial Code Provisions of the state designated in the contract, you should ask an attorney to look it up for you.

5. *Delivery*

QS/1 has no mention of delivery dates in its papers. Compute-Rx on the other hand has a clear place in the contract to indicate the date of installation.

It's vitally important to have a delivery date written in the contract. Sometimes there are conditions beyond the control of the seller of computers and they cannot deliver even on agreed upon dates. Nevertheless, you can also build in penalties for failure to deliver if you have hired extra staff and have taken extra time to be ready to receive a computer when it is not going to be made available to you.

QS/1 says there will be transportation charges of approximately $75 whereas Compute-Rx delivers without charge.

It is important to discuss delivery, uncrating and date of installation with each of the sellers that you are discussing the possible purchase of a computer. Note that the Compute-Rx contract requires the customer to be responsible for providing a proper operating environment and to take full responsibility for its installation. While Compute-Rx gives free installation on one hand it also requires the legal responsibility to be with the customer. Perhaps this creates enough ambiguity to make one wonder what you are getting for free if you are responsible for it.

6. *Acceptance*

It is elementary contract law that the contract requires an offer, consideration and acceptance. But when does acceptance take place? The QS/1 Agreement states that it is accepted upon acceptance by the Smith Data Processing Company. Compute-Rx, on the other hand, does not define a time of acceptance. Under Maryland Law and most uniform commercial code provisions in other states, a buyer can revoke acceptance within a ''reasonable time'' after the buyer discovers or should have discovered that the goods received are not the goods purchased.

This means that when you install a computer system you need to begin working with it right away inorder to determine if it is what you bought. If it is not the same system that you were sold, you should notify the company in writing by certified mail and be prepared to consult an attorney to firm up your ability to present your position.

7. *Payments*

Under the QS/1 Agreement failure to pay charges when due gives the company the right to terminate the agreement. QS/1 wants a deposit of $2,000 on the system when the agreement is signed with a balance to be paid at the time of installation. Compute-Rx requires that the purchase price be paid at one time or that you agree to lease the equipment and pay for software licenses as priced at the same time.

8. *Taxes*

Both companies charge sales tax on the total purchase price. Since these are canned software programs, there is little likelihood of avoiding to pay the sales tax on the software. In some cases computer software can be purchased without paying the sales tax if it can be proven that the software was custom made, thereby becoming a service and not a product sale.

9. *Maintenance/reliability*

Both companies offer as IBM AT Computer. So reliability will be just as good as IBM can make it. QS/1 software does not include price updates or drug interactions and therefore it has fewer things that can go wrong when making records, doing analysis and so forth.

QS/1 charges $650 per year for software maintenance agreement and an equipment maintenance charge of $51.08 per month. Compute-Rx, on the other hand, charges a total of $163 for hardware and software monthly maintenance and $45 for price and drug interaction updates for a total of $208 a month.

QS/1 wants you to do a service check on the machine yourself and if it is determined that it needs service then you may mail in the computer for service. You are responsible for packing the machine in its original packing materials or purchase new materials from QS/1. Alternatively you could sign a separate on-site amendment and QS/1 will come to you to do the repairs.

Compute-Rx will do two preventive maintenance inspections per year and do remedial maintenance at those times or when you call in for service on-site, all within the $208 per month service charge.

10. *Software and software documentation*

Neither of the companies provided complete software documentation with their contracts. However, this is a very important part of the purchase. You have to be familiar enough with the written users manual to know whether the words in the manual matches the words on the screen when you are operating the programs or whether there are significant differences between the software and the documentation.

Suppose you have a pharmacy system which keeps track of inventory and prepares patient accounts for monthly statements and annual tax reports. If any module is added to it to do medicaid billing or nursing homes, this could have the effect of creating some bugs in the daily operating software program. Should it do so, you will have to be prepared to spend extra money for technicians to straighten out these difficulties.

With the Compute-Rx program modules, one would think this would not be a problem. However, these kinds of bugs do develop and it's best to be advised about them in advance. If you have any idea you will be needing extra kinds of software on your computer, it is probably a good idea to purchase it up front and have it installed at the same time to avoid later difficulties.

11. *Confidential proprietary information*

As we said earlier QS/1's Agreement is a basic licensing agreement which ties you down to using, and not buying, their programs during the term of the license. The contract provides that you agree to keep it confidential and not copy it except for your own use. And QS/1 wants you to indemnify the company for any patent or copyright infringements. This means if they can prove you sold it to somebody or adapted their program for other uses they may have a right to go for damages against you.

Compute-Rx, while not a specific licensing contract, covers licensing very carefully. The contract states that the customer is granted a personal non-exclusive right and license to use the software program and the buyer agrees not to reproduce it except for his own use.

12. *Disclaimer related to Data Bases*

Neither of the contracts reviewed for this article contain any disclaimer related to specific Data Bases. The Compute-Rx system is the one that adds the monthly charge for updates or drug interactions and prices.

The general limitations on liability and warranties apparently are designed to cover data base updates and these side programs as well as the basic software program.

Computers will not absolve pharmacists of their professional responsibility to exercise individual judgment about drug interactions. Simply because the computer program has not been properly done to catch every injury-causing interaction does not mean that the pharmacists by themselves are going to be absolved of liability. It is a good idea to know your computer program thoroughly so that you can rely upon its accuracy. Simply because it is stated 61,000 different drug interactions are programmed in the computer system, they are not necessarily all correct in every case. You need to know where the deficiencies of such programming are and be prepared to make your judgments about them known to your patients.

Final Comments

Both these systems use twenty megabite computers and the Compute-Rx system has a tape backup which will help you protect and store at least a part of your data away from the computer.

The contract documents for QS/1 do not describe how many patients, prescriptions, doctors or other data elements you can enter into the system. In the case of Compute-Rx the sales agreement does not contain statements about the specific quantities of data storage capacity. However, the sales literature accompanying the contract indicates that it will hold 90,000 prescriptions, 15,000 patients, 1,000 doctors, 4,000 drugs, and up to a 1,000 direction abbreviations for printing on prescription labels.

Both of these firms offer 800-number, toll free service and I would recommend against buying any computer system that did not offer such a service. There will be times at the beginning of operations and times when new personnel are being trained on the equipment or program that new questions will come up. It is always best to have a free source of help to solve these problems before the next prescription goes out the door.

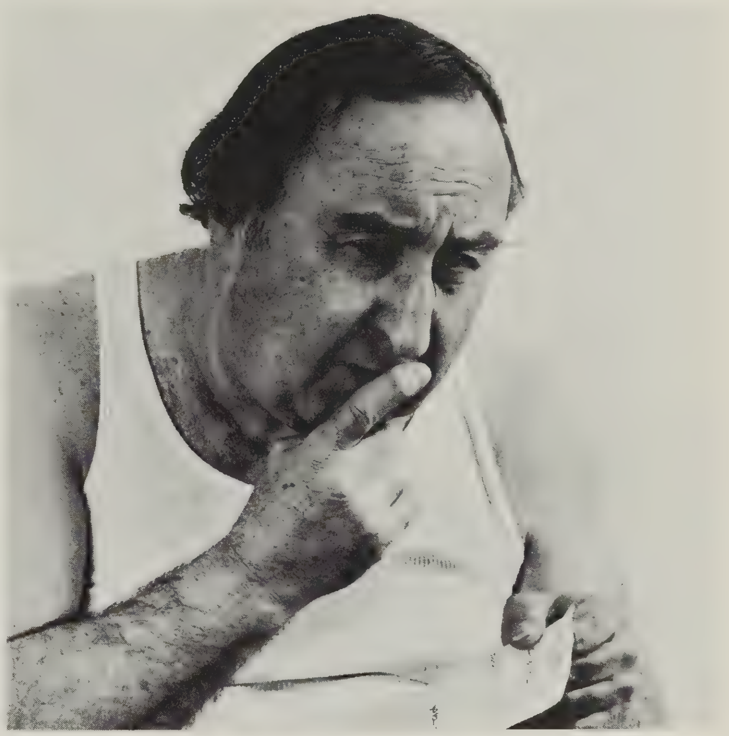
Both the QS/1 and the Compute-Rx systems seem to be adequate for most pharmacy uses. The Compute-Rx system, of course, comes with additional program modules and seems to have a little more dazzle. However, if your pharmacy is doing very little medicaid or third party billings, it would seem that either of these systems will speed up and make your work more accurate. Based on a review of their contracts, I can recommend that pharmacists give both companies a thorough review before deciding what to buy.

For more information about QS/1 Data Systems contact Ken Couch, Pharmacist, Director of National Marketing at Smith Data Processing, P.O. Box 6052 Spartenburg, South Carolina 29304 and for Compute-Rx contact Allen Novak, Pharmacist, at Allen Novak & Associates, 8235 Hermitage Road, Richmond, Virginia 23228.

For a copy of the addresses of the eight other pharmacy computer system companies that provided contracts in 1983, you may write to the author at the Association Office or dig into your files for the September 1983 issue of *The Maryland Pharmacist*.

A great many pharmacists have not yet chosen to go with a computer system for their dispensing operation. It seems clear that the independent pharmacists will be forced to install a computer if they wish to survive in the competitive market place today. While at $15,000 to $20,000 the cash outway seems like a lot, when you amortize it over a ten year period, and with the expected increase productivity that you will obtain, the price is a small one to pay for continuing to maintain successful pharmacy practice and making it more efficient.

How well are you communicating with your PATIENTS?



Patient compliance—how well patients follow instructions about taking prescription drugs—is something that worries health professionals, according to a recent Harris survey. And with good reason. A number of studies have shown that a third to a half of all drugs are taken improperly. Yet a Chilton survey found that only 2 to 4 percent of patients question their doctors about drugs prescribed for them.

It's up to health-care providers to open up the dialogue about prescription drugs. When you write, dispense or check on a prescription, make sure your patient knows:

- **The name of the drug**
- **Its purpose—what conditions does it treat?**
- **How and when to take the drug—and when to stop taking it**
- **What food, drinks and other drugs to avoid while taking it**
- **What side effects may result—are they serious, short-term, long-term, etc.?**

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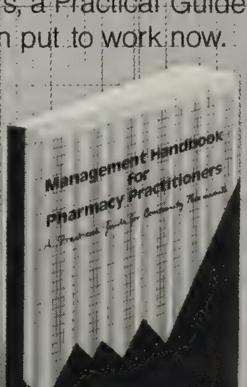

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The Pharmacy Space Soap Opera

by Buck Rogers, P.D.
Space pilot and Association Manager

set The interior of a futuristic Pharmacy space ship named the Star Ship "Free Enterprise." All cast members dressed as Pharmacists.

cast
- —Captain Quirk, Captain of the "Free Enterprise."
- —Luke Skywater, First Technician
- —Commander Stock, Vulcan First Officer
- —E.T.R.2, cute little computer with strange ideas.
- —Commander Bonz, Ship's Medical Doctor
- —Varth Dader, a really bad guy.

dialogue

(Announcer off stage) Leading a rag tag band of pharmacists away from Cylon Tyranny, the Star Ship "Free Enterprise" searches for a distant shining planet known as "Profit."

(Capt. Quirk) Yes, Luke Skywater, I can certainly tell you that leading this rag tag band of pharmacists to find the planet "Profit" sure isn't easy. I swear sometimes these pharmacists will never find "Profit."

(Luke Skywater) Well, Capt. Quirk, there have been a number of difficulties that our rag tag band of pharmacists have had to face. Remember when the Cylon's used their Homo ray on our sister space ship "Independent Owner?"

(Capt. Quirk) That wasn't a Homo ray, that was an "HMO ray," and you are right, it did nearly destroy our warp drive! But, of course that was nothing compared to the Klingons with their "Third Party Phazer Delays." That was really a terrible experience. The Delays penetrated every part of our ship "Free Enterprise" and choked our life support systems with a series of irregular cycles for payment and late price updates. But, worst of all, it secreted a particularly deadly form of the alien life form, "the red tape worm." It was awful.

(Skywater) I sometimes get the funny feeling that the "Free Enterprise" is headed down the tubes with all of the trouble we have had lately.

(Capt, Quirk) Not to worry Skywater. We have lots of capable help in the form of First Officer Commander Stock and the cute little computer "E.T.R.2".

(Skywater) Isn't that "D.T.C.3"

(Capt. Quirk) I don't think so, unless he's changed his numbers again. At any rate—here they come. . . .

(Enter Mr. Stock with the cute computer E.T.R.2)

(Stock) Captain, I am afraid we have more trouble on the "Free Enterprise" which is leading this rag tag band of Pharmacists to the shining planet known as "profit."

(Capt. Quirk) What is it Stock—I can take it.

(Stock) Captain, you remember when the Romulans hit us with the Medicaid Ray, I thought it might be an "inside job?" (Quirk nods) Well I have growing fears that there has been a plant inside the starship "Free Enterprise".

(Capt. Quirk) Of course there's a plant inside the "Free Enterprise", That's how we breathe.

(Stock) Not that kind of plant Captain. I am referring to a turncoat, a stooge, a fink, a traitor, a Nazi, Attila the Hun, the scourge of humanity, a pimple on the - - - -.

(Capt. Quirk) Okay Stock, I get the picture.—What can we do to capture the villain?

(Stock) I have a plan, Captain, and I think we should consult with E.2.T.2.

(Quirk) He's changed his name again?

(Stock) Wouldn't You? (Turns to E.2.T.2) Let's hear your report.

(E.2.T.2.) As a former community Pharmacy Computer from the Space Ship "Independent Owner," I must concur with Commander Stock. "The fault, dear Brutus, lies not in our stars, but with ourselves."—to quote a little Buck Rogers. Listen Captain, I have seen it all. You know that even if the Star Ship "Free Enterprise" runs into a series of reimbursement astroids, the force is still with us. There *will always* be a force. And there will always be Pharmacy. We are like a nova spreading light throughout the dark domains of physician dominated health care galaxies. Come—kneel close to our healing consultations! Feel the uplifting nature of our patient profiles! Bask in the knowledge that we educate for free, compound for free, consult for free, advise for free and still manage to survive the sling and arrows of outrageous fortune—not to mention insignificant dispensing fees.

(Stock quickly turns E.T.R.2 off)

(Capt. Quirk) Stock, I think you'd better take Stock of this situation and don't give me a Stock answer.

(Stock) Pardon, Captain.

(Capt. Quirk) I think this machine is about due for its 6,000 mile checkup. I can't believe that R.2.T.3., or whatever it calls itself this week, really thinks we can lead this rag tag band of Pharmacists to the shining planet known as "Profit" by giving away everything except the product. I think he has a screw loose.

(Stock) I'll check, Captain. (Stock leaves)

(Skywater enters) Well Captain, I see that Pharmacy's Stock is rising.

(Capt. Quirk) What are you talking about, Commander Stock was just here and he's the same height he has always been.

(Skywater) I tell you Stock is rising, Captain.

(Capt. Quirk) Skywater, have you been smoking the laundry detergent again? Stock may have funny ears but he's the same size as before.

(Skywater) Not him, Captain, the Pharmacy stock—you know—price rises. It's happening again all across the board. I'm afraid we may have to use the Return Goods Photon Torpedos on them.

(Capt. Quirk) Egad! Not that. I hate dealing with outdated, overpriced merchandise.

(Skywater) Don't over act Captain. Besides, we may be able to use our new Generic Drug Force Field to help lower those prices.

(Enter Ship's Doctor, Commander Bonz)

(Bonz) Captain, I think we have even more problems. An ugly roomer has sprung up on the good ship "Clinical Pharmacy." Some of their crew say that the only way we will ever find the shining planet "Profit" is by (gasp) practicing Medicine!

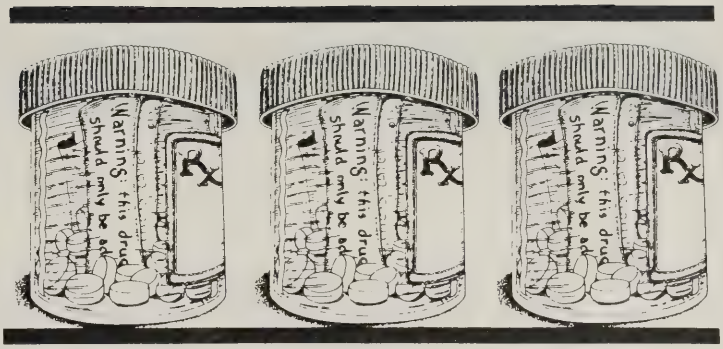
(Capt. Quirk) Easy Bonz. Don't take it so hard, these are desperate times for this rag tag bunch of pharmacists. Its only natural that they would take to the ancient arts to find relief from their present circumstances.

(Bonz) They'll practice Medicine over my dead body.

(Capt. Quirk) To tell the truth, Bonz, I've practiced Medicine myself from time to time and it hasn't been so bad. I've always wondered, though, when you guys would stop practicing and learn to do Medicine right the first time.

(Bonz) Well, this TriCorder has taken all the fun out of malpractice anyway.

(Capt. Quirk) By the way, some crew members of the "Clinical Pharmacy" wanted to talk with you in sick bay. Something about "therapeutic interchange", "patient assessment", and "dosage titration." I don't understand all of this Medical jargon most of the time.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(Bonz exits)

(Enter Varth Dader—Dressed in Black Cape as a Pharmacy Inspector)

(Dader) I have found you at last Captain Quirk. Prepare to join the Force.

(Capt. Quirk) Just a minute Varth Dader. I know from watching "Star Snores" that I have nothing to fear but fear itself—so do your worst.

(Dader) Actually, Captain, that is not true. Commander Stock was right, there is an enemy within.

(Capt. Quirk) Oh no, it can't be—not this loyal rag tag band of Pharmacists. Not after all we have been through together!

(Dader) Don't over act, Captain. What would you call those who never support their pharmacy associations but complain loudly all of the time?

(Capt. Quirk) Why, I guess I'd have to call them non-member Romulan finks.

(Dader) Right, and you have just described many of those in your rag tag band of Pharmacists. They don't really want to find the shining planet "Profit" because they are having too much fun fighting among themselves. If I were you, I'd take a Phazer and blast them all.

(Capt. Quirk) What happens when you get hit with the beam of a Phazer?

(Dader) You get "Phazed Out." Of Course.

(Capt. Quirk) Gasp! Oh no. Not that, a fate worse than death.

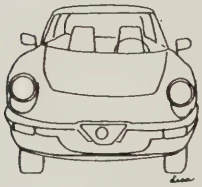
(Dader) That does it Captain Quirk. You have over acted one last time. Take That.

(Dader beats on Quirk with pill tile and both exit into the sunset—or whatever)

The End

national scene

Driving Impairment



The body of knowledge regarding the effects of psychoactive drugs on driving ability is not yet sufficient to develop legal guidelines like those that exist for alcohol, a National Institute on Drug Abuse (NIDA) consensus conference has reported. The authorities convened by the federal agency agreed that studies are needed that demonstrate dose-related impairment of skills, drug concentrations related to impairment degree, confirmation of impairment by highway experience, and reliability of roadside tests.

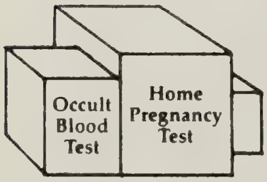
Criteria such as these have been met for ethanol, the conferees said, but it is not certain that they can be met for other drugs such as marijuana which are now of major concern to highway safety experts.

Women in Science

Women are being discouraged from seeking science-related careers because of discrimination in the work force and stereotyped career expectations, reports a U.S. Congressional agency. The Office of Technology Assessment said female scientists and engineers generally receive lower salaries and have a smaller chance of promotion than men.

"Women's salaries are significantly lower than men's in almost all fields of science, in every employment sector and at comparable levels of experience," the agency said. "In academia, men are far more likely than women to hold tenure-track positions, to be promoted to tenure, and to achieve full professorships...The differential treatment of women in the work force most directly violates the principle of equality of opportunity because it affects people who have established, by virtue of obtaining an advanced degree, the right to pursue a scientific or engineering career based solely on the quality of their work."

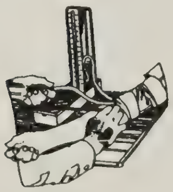
Home Diagnostics



The home diagnostic test market is not brand-oriented, according to a recent survey of 150 pharmacies conducted by Market Technology Group, a consulting firm in Stamford, CT. The firm noted that while "home diagnostic tests for diabetics were generally requested by brand name, all other kinds of tests were not." The firm observed that occult blood tests, for example, were requested by brand name by only 15% of purchasers. Home pregnancy test kits were requested by brand by 37% of purchasers, and by type of test kit by 56% of purchasers.

Widely stocked product categories were home pregnancy tests (available in 95% of the pharmacies), blood pressure monitors (89%), occult blood tests (71%), and tests for urine glucose (99%), blood glucose (97%), and urine protein (70%). The firm estimates that the home diagnostic market, aside from diabetes, blood pressure, and temperature testing, is between $400-500 million a year, and that it will reach $1 billion by the early to middle 1990s.

Calcium Claims



Last year, David McCarron of the Oregon Health Sciences University drew widespread attention for his epidemiology-based claim that calcium intake was inversely related to blood pressure. Now McCarron has conducted a clinical study of the precise effects of calcium supplementation in hypertensive patients, in which experimental subjects took 1,000 mg calcium carbonate or citrate per day for eight weeks.

The subjects showed some modest gains in decreasing blood pressure, in the aggregate, but when the data are broken out what becomes apparent is a pattern in which some patients showed real improvement in high blood pressure, many were unchanged, and some actually had their pressures raised. Despite these findings, pharmacists should recognize that patients may try to self-treat their own high blood pressure with calcium supplements, given their ready availability and lure of being a "natural" alternative to hypertension medications.

Provided as a service by the American Pharmaceutical Association

99TH CONGRESS, SECOND SESSION

Pharmacy Legislative Update

Of the nearly 8,000 measures introduced in the first session of the 99th Congress (Jan.-Dec. 1985), 240 became law. Included were bills establishing "National Hospice Month" and "Drunk and Drugged Driving Awareness Week" and appropriations for many federal agencies. The President also signed bills eliminating the onerous IRS vehicle recordkeeping law, amending the orphan drug program, and re-establishing payment of legal fees to pharmacies and other small businesses victimized by federal government abuse.

Below is an update of several pending bills of importance to pharmacy. In addition to these, it is expected that the House Energy and Commerce Committee will begin action this session on a variety of legislative recommendations based on the final drug diversion report of its Subcommittee on Oversight.

BILL	STATUS
FTC Act S 1078, HR 2385	House/Senate conference to be held on two bills that both include provisions to require FTC action on predatory pricing (See H. Rpt. 99-162)
Federal Polygraph Ban HR 1524, HR 1924, HR 1792, HR 3916, S 1815	HR 1524 was amended by a 20-9 vote to preserve freedom of choice for CSA registrants in cases of theft or diversion. House vote likely this session (See H. Rpt. 99-416)
FDA Approval on Label HR 2244	House passed without objection 6-85; pending before Senate Labor Committee (See H. Rpt. 99-143)
Pilot Heroin Program for Cancer Victims HR 1597, S 70	Pending before House Energy and Commerce and Senate Labor Committees
Export of Unapproved Drugs S 1848, HR 3962, HR 3995	Amend bill reported 12-85 to Senate (see Sen. Rpt. 99-229); pending before House Energy and Commerce Committee
Medicare Home Coverage for Long-term IV Antibiotic Therapy HR 1215	Pending before Ways and Means and Energy and Commerce Committees
Designer Drugs S 1437	Passed Senate 12-85; pending before House Judiciary and Energy and Commerce Committees
To Require Senate Approval of FDA Commissioner HR 3903, S 2025	Pending before Energy and Commerce and Labor Committees
Restitution for Victims of Federal Crimes HR 2213	House passed 10-85 (see H. Rpt. 99-334); pending before Senate Judiciary Committee
PPO Act HR 233	Pending before House Energy and Commerce Committee
Reyes Syndrome Act HR 1381, S 538	Pending before House Energy and Commerce Committee and Senate Labor Committee
Sulfite Safety Act HR 1427, S 573	Pending before House Energy and Commerce Committee and Senate Labor Committee
Collection of Tax on Mail Order Sales HR 3549, S 1510	Hearings held by Senate Finance Committee (11-85); pending before House Ways and Means Committee
Deficit Reduction Act, Including Provisions on Hospice, DME Rent/Purchase Freeze, and Medicare Part B Appeals HR 3128	House/Senate conferees failed to agree 12-85

Copies of these bills and related documents are available from the NARD Legislative Clearinghouse, 205 Daingerfield Road, Alexandria, VA 22314.

FYI, a monthly perspective on topics of interest to pharmacists, is provided as a service by the National Association of Retail Druggists.

1986 Tax Dates

The following are due dates for federal and state taxes that most affect you. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart. Note that if a tax is due on a weekend or holiday, the due date is advanced to the next business day, causing some taxes due the last of the month to be payable early next month.

April 1986

Thursday, April 3	FD(a)
Tuesday, April 15	FD(b), FC, FI/SI, SC Federal and State Individual Income Tax due or you must pay estimated amount due and file for an automatic four month extension. Interest will be paid on amount paid after April 15. State personal income tax due.
Monday, April 21	ST
Wednesday, April 30	FQ, FU, FD(c), SQ, SU

May 1986

Monday, May 5	FD(a)
Thursday, May 15	FD(b)
Wednesday, May 21	ST

June 1986

Wednesday, June 4	FD(a)
Monday, June 16	FD(b), FC, SC, FI/SI
Monday, June 23	ST

July 1986

Thursday, July 3	FD(a)
Tuesday, July 15	FD(b)
Monday, July 21	ST
Thursday, July 31	FQ, FU, FD(c), SQ, SU

August 1986

Tuesday, August 5	FD(a)
Friday, August 15	FD(b) Last day for filing tax return by individuals who obtained an automatic 4 month extension.
Thursday, August 21	ST

September 1986

Wednesday, September 3	FD(a)
Monday, September 15	FD(b), FC, FI/SI, SC Last day for filing tax return by corporations that obtained an automatic 6 month extension.
Monday, September 22	ST

October 1986

Friday, October 3	FD(a)
Wednesday, October 15	FD(b)
Tuesday, October 21	ST
Friday, October 31	FQ, FU, FD(c), SQ, SU

November 1986

Wednesday, November 5	FD(a)
Monday, November 17	FD(b)
Friday, November 21	ST

December 1986

Wednesday, December 3	FD(a)
Monday, December 15	FD(b), FC, SC
Monday, December 22	ST

FD(a)	Last payment due on federal income and social security taxes withheld during the previous month if over $3,000 was withheld. You are required to deposit the amount withheld within 3 banking days after you reach $3,000 at the end of any eighth-monthly period (these periods end on the 3rd, 7th, 11th, 15th, 19th, 22nd, 25th, and last day of the month).
FD(b)	Federal income and social security taxes withheld must be deposited by this date if between $500 and $3,000 was withheld during the previous month. Earlier deposit is required when $3,000 is reached prior to this date.
FQ	Federal Quarterly income and social security taxes withheld must be paid.
FU	Federal Unemployment tax must be paid.
FC	Federal estimated corporation taxes must be paid if on calendar basis (note—fiscal year corporations pay this tax on 15th day of 4th, 6th, 9th, and 12th month of their year).
FI/SI	Federal and state estimated individual tax for previous quarter due.
FD(c)	Federal social security and withholding tax due on domestic workers.
ST	Maryland State Sales Tax due.
SQ	Maryland State income tax withheld due for previous quarter.
SU	Maryland State Unemployment taxes due.
SC	Maryland State Estimate of corporation tax due.

Prepared as a courtesy to Maryland Pharmaceutical Association Members, by C. W. Amos & Company. Certified Public Accountants with offices in Annapolis (269-1803), Bethesda (654-3044), Cambridge (228-7400), Salisbury (742-1328), and Baltimore (727-5341).

The Annual Dinner of the Alumni Association was held January 19th at Martins Eudowood in Baltimore. State Senator Joseph Bonvegna (left) receives the Honorary President's plaque from George C. Voxakis (right)

martin's
EUDOW

John Toll, President of the University of Maryland told the gathering that the School of Pharmacy has the fastest growing membership in the President's Club due to the David Stewart Associates campaign.

martin's
Eudowood

The dinner program feature a presentation from Paul Starr on "Applications of Hypnotherapy in Medicine."

Alumni Association President, Karen Lewis, presided over the meeting.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

DILTIAZEM: Digoxin (Lanoxin) levels are found to be increased when the glycoside is used concomitantly with some antiarrhythmic agents and calcium channel blockers. Since interactions with nifedipine (Procardia) and verapamil (Calan, Isoptin) have been described, it was of some interest to determine if such an interaction occurred between the newest calcium channel blocker diltiazem (Cardizem) and the glycosides. A study conducted in 24 healthy males suggests that no alteration in either kinetics or apparent volume of distribution occur during concomitant use. *Clin Pharmacol Ther,* Vol. 35, #2, p. 183, 1984.

ACETYLCYSTEINE: Several years ago, acetylcysteine (Mucomyst) was approved for use in treating patients demonstrating acetaminophen toxicity. Several cases of anaphylactoid-like reactions have been reported. The usual allergic reactions appeared and all patients recovered. Overdoses were also reported and produced signs of rash, angioedema, hypotension and bronchospasm. *Br Med J,* Vol. 289, #6439, p. 217, 1984.

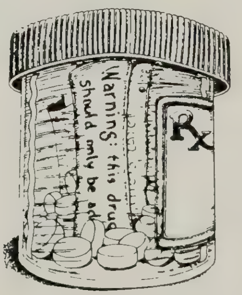
HYDRALAZINE: Lupus reactions have been associated with hydralazine (Apresoline) administration. A prospective study has shown that the development of this condition is dose dependent. No lupus was reported in patients receiving 50 mg of hydralazine per day, but 5.4% experienced the eruptions while taking 100 mg per day, and 10.4% developed lupus at doses of 200 mg per day. The incidence was greater in women than in men. Women taking 200 mg of hydralazine per day for three years have approximately a 20% chance of developing lupus. *Br Med J,* Vol. 289, #6442, p. 410, 1984.

PROCAINAMIDE: The antiarrhythmic agent procainamide (Pronestyl) is eliminated partially via active secretion by the kidney into the urine. The plasma level of procainamide correlates with the pharmacological activity so factors which alter the concentration of procainamide become important in predicting clinical response. Cimetidine (Tagamet) has been associated with increased plasma levels of some drugs, so it was administered to a group of male volunteers along with procainamide to evaluate the likelihood of a possible drug interaction. Results suggest that cimetidine administration does increase the plasma concentration and half-life of the antiarrhythmic agent, but does so as a result of reduced renal clearance rather than an alteration in metabolism. *Clin Pharmacol Ther,* Vol. 36, #2, p. 221, 1984.

DEXAMETHASONE: A double blind, randomized, crossover study compared the antinauseant effects of prochlorperazine (Compazine) with those of dexamethasone (Decadron). The phenothiazine was utilized in a dose of 10 mg given intravenously 30 minutes before administration of chemotherapeutic agents and then followed by 10 mg of the drug orally every six hours for a day. Dexamethasone was given in doses of 20 mg intravenously one-half hour prior to chemotherapy and then used orally in 10 mg doses every six hours for 24 hours. The most common side effect was somnolence (prochlorperazine = 60%, dexamethasone = 12%). Loss of appetite was experienced more often by patients receiving prochlorperazine. Overall the effectiveness of dexamethasone was found to be superior to that of the more conventional antinauseant. It should be pointed out that the potent nauseant cisplatin was not administered to the study group, but agents such as cyclophosphamide, methotrexate, and fluorouracil were included. *N Engl J Med,* Vol. 311, #9, p. 549, 1984.

HIGH DENSITY LIPOPROTEINS: High density lipoproteins are associated with a reduced risk of cardiovascular mortality. Athletes have elevated levels of these fats and investigators have suggested that the levels are high because the athlete converts more lipid to high density lipoproteins via increased lipoprotein lipase activity. Additionally, the activity of their hepatic lipase may be reduced and the beneficial proteins may exist longer because of reduction in their clearance. *JAMA,* Vol. 252, #8, p. 1034, 1984.

We regret to inform the readership that this will be the last ''Abstracts'' Column in the *Maryland Pharmacist* due to the cancellation of ''Pharmaceutical Trends'' published by the St. Louis College of Pharmacy, from which it was excerpted. We would welcome any suggestions for alternative sources for this information so that we might continue this popular feature.



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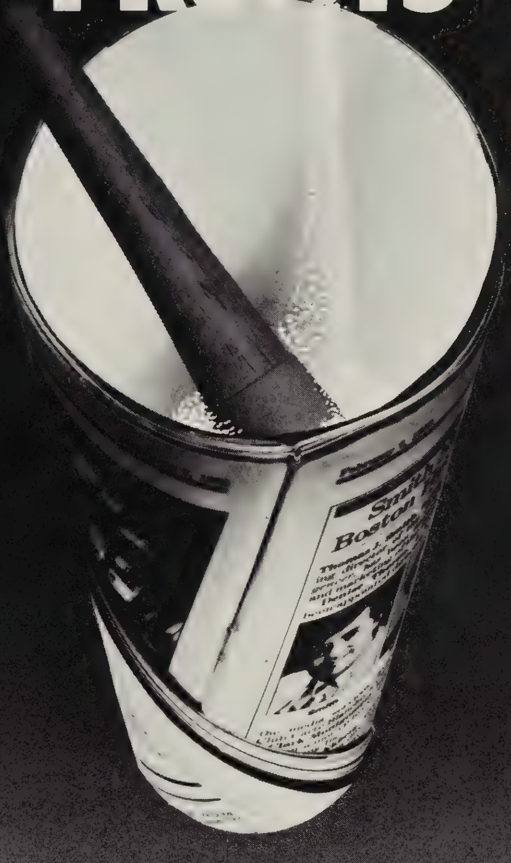

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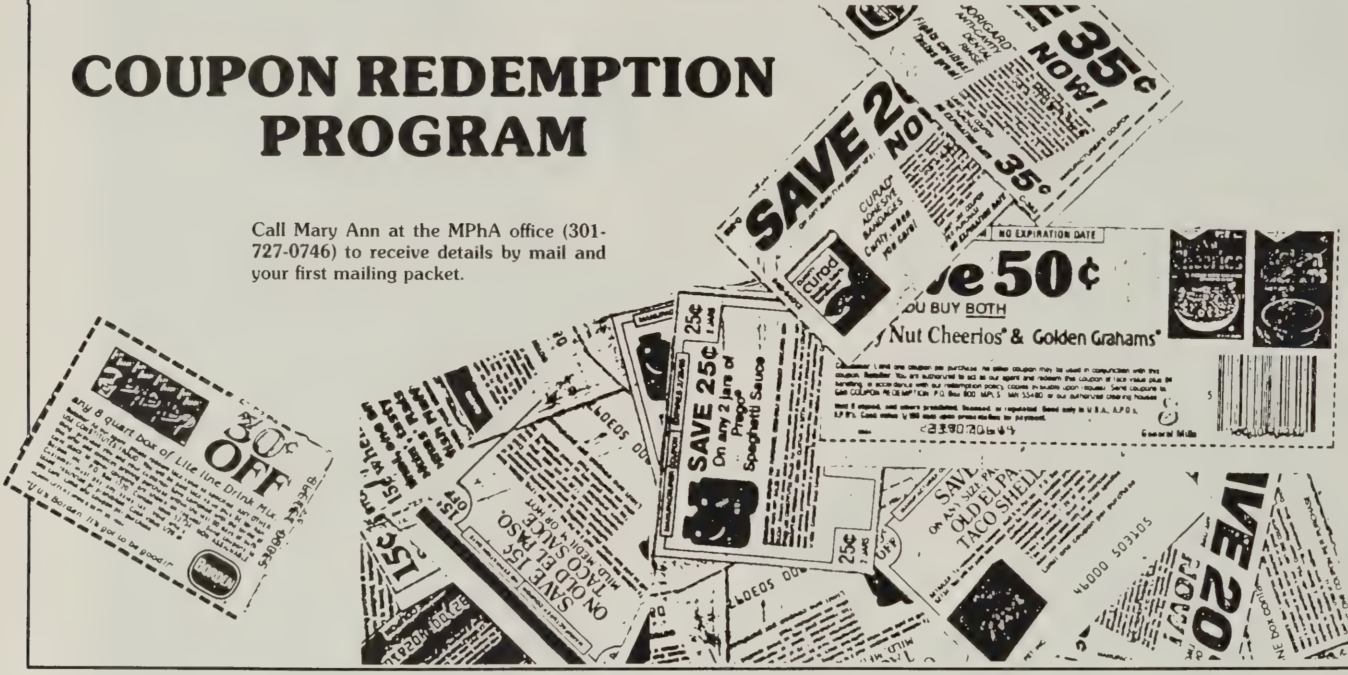
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May 4—Alumni Association Graduation Banquet
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May 23—School of Pharmacy Commencement Exercizes
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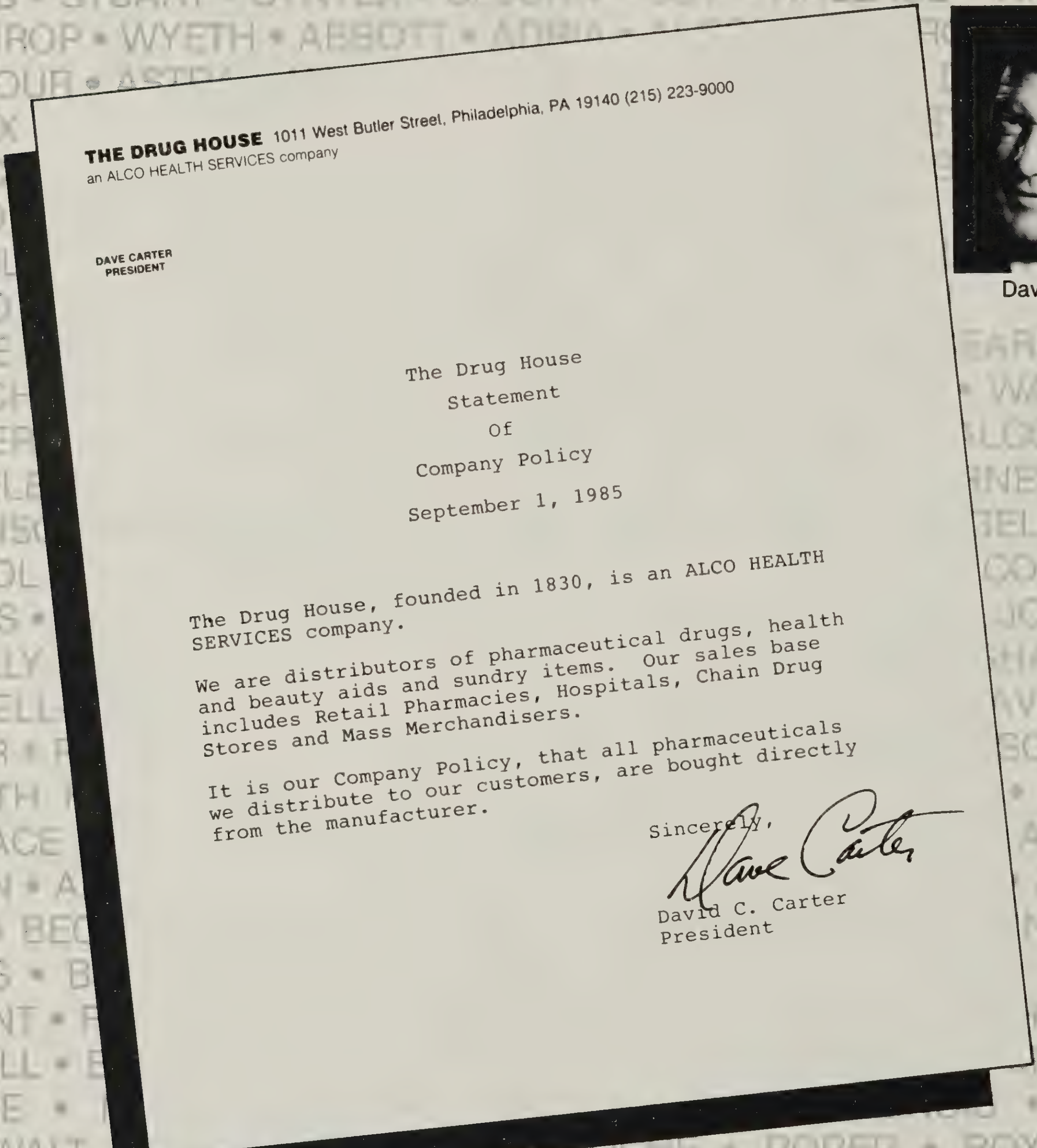

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THE
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May, 1986
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NO. 5

OTC Vaginal Douche Products

— Thomas A. Gossel
— J. Richard Wuest

Elder Ed Talk III

— Madeline Feinberg

Convention Preview Highlights

Pharmacy Around the World

—Grady Dale

Timely Topics — Osteoporosis

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President's Message

Larry Young

I will paraphrase . . .

"The single most important issue for a politician is to be re-elected. Votes count. Bodies count." Politicians are extremely sensitive to letters, telephone calls, and most of all, to body counts. So if you have an issue which you think is important enough to warrant legislative action, and you have found a sponsor for your bill, then your work has just begun.

For example, this association sponsored a bill which would severely restrict physicians from dispensing prescriptions for profit. No need to argue the merits of this bill from pharmacy's perspective, the consumer's perspective, and even the physician's perspective, in most cases. In fact, most of the opposition to the original bill as written was eliminated through amendments which still left the bill intact as it is aimed at the community-based physician dispenser. But the opposition, Physicians' Pharmacy Services is grossing $250,000 a month in sales to physicians, and they put up a good fight for this bill, calling in physicians and consumers who do not believe doctors should be subjected to limitations on their right to practice medicine.

As I write this editorial, the bill is up for grabs in the House of Delegates. I do not know the outcome as we go to press.

But the lesson to pharmacy has been learned! With Larry Young leading the charge, and other delegates as well, we are told the opposition lobbied heavily for the bill. "We haven't heard from the pharmacists," they say, "not *before* this issue came up, nor even *now*."

I frantically called pharmacies for support. Pharmacists do not even know what district they live in. They don't even know who their delegates are! Many do not even know the difference between their senators and representatives in Congress and in Annapolis! They better know now!

If we lose this bill, blame yourselves. If we win this bill, thank Dave Banta, Jud Garrett and the very small handful of pharmacists who took the time to work, on some days round the clock, to fight the avalanche of letters, calls and personal appearances orchestrated by the opposition.

We gratefully acknowledge the support of Del. Larry Young, Senator Dennis Rasmussen, Sen. Steinberg, Del. Ben Cardin for their conviction and dedication to our cause. Most importantly, I thank office staff, Beverly and Maryann for their exhaustive efforts on our behalf.

* * * *

An addendum:

Don't ever make the mistake of thinking that "right" or "wrong" decides what will become law. Because even if the facts are evident to all the players, the opposition may be desparate enough to deliberately distort (I am being polite) the issue to win the votes. The AARP Pharmacy Service mailed a letter to AARP members in Maryland (see page 20) which clearly did not represent the issue of regulation of mail order pharmacies serving citizens of Maryland. The Senators were completely aware of the distortions but were helpless against the letters, calls and the elderly who stalked them demanding the bill be defeated. "Sorry, Dave. This is an election year." So H. B. 1465 was killed in committee. Where were you?

Madeline Feinberg,
PRESIDENT

Editors Note: SB 830, the bill to discourage Physician Dispensing, did pass both Houses of the General Assembly and, at press time, awaits the Governors signature into law. The June issue of this Journal will carry the actual language of this and several other bills affecting pharmacy in the annual legislative wrap up issue. A special insert in the April Newsletter will discuss the effect of these bills and will give the actual Committee vote counts. It is important to thank any legislator you know who voted for SB 830!

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 4

Advising Consumers on OTC Vaginal Douche Products

by **Thomas A. Gossel, R.Ph., Ph.D.**
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, OH

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to:

1. outline the FDA/OTC advisory panel's recommendations on douching solution ingredients and douching equipment;
2. explain the factors involved in maintaining a healthy vaginal tract;
3. outline the proper method for douching.

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Objectives

At the conclusion of this lesson, the successful participant should be able to:

1. explain the relationship of various factors important for maintaining a healthy vaginal environment;
2. cite specific recommendations of the FDA/OTC advisory panel that reviewed data on the safety and effectiveness of OTC douching ingredients;
3. exhibit an understanding of the various methods for using a douche solution;
4. differentiate between drug and cosmetic claims for OTC douche ingredients;
5. specify potential dangers involved with douching during pregnancy.

Over-the-counter douche products are big business in the U.S. Sales of solutions and powders for making solutions to rinse the vaginal tract were reported to be nearly $20,600,000 during 1983. Various surveys state that over one-half of all American women douche regularly. While some douche products are intended to be used solely for cosmetic purposes, others are indicated for therapeutic purposes.

Although many women douche regularly, factual information on the correct procedure is difficult to find. Few articles have appeared in the medical/pharmaceutical literature or consumer magazines that illustrate the proper method for douching.

Whether or not a woman should douche in the first place, and the correct procedure to follow when it is indicated are the topics of this month's lesson. Additionally, the recommendations of an FDA advisory panel that reviewed OTC vaginal drug products are presented.

Vaginal Physiology

The normal pH range of vaginal fluids is 3.0 to 5.5 during the reproductive years. Fluctuations are normal and coincide with various phases of the menstrual cycle. For example, the pH is less acidic around ovulation and during menstruation than at other times.

The pH of the vaginal tract is controlled, in part, by the indigenous microflora which consist of numerous microorganisms including cocci, coliform, diphtheroids, anaerobes, fungi, lactobacilli, and trichomonads. Acidity is maintained by bacteria, notably the lactobacilli which produce lactic acid. They do this by converting glycogen contained in vaginal epithelial cells to lactic acid. An acidic media is necessary for the preservation of normal growth of the vaginal flora and to confer some protection against overgrowth and invasion by pathogenic microorganisms.

At times, certain microorganisms may overgrow and cause infections resulting in vaginal odor, discharge, and irritation. Since so many different microorganisms normally inhabit the vagina, it is difficult to casually determine which one is responsible when these symptoms are present. Thus, it is also difficult to assess which therapy, if any, is best.

Another important point about the vaginal lining is that many drugs can be absorbed through it into the general circulation. The amount absorbed may be sufficient to cause toxicity to the woman, or to her fetus if she is pregnant.

Vaginal Douches

The term "douche" means to cleanse. Therefore, a **vaginal douche** is a liquid preparation used to irrigate the vaginal tract. It is intended for one or more of the following purposes: 1. cleansing, 2. producing a soothing or "refreshing" sensation, 3. deodorizing, 4. relieving minor irritations, 5. reducing the number of pathogenic microorganisms, 6. altering the pH to encourage growth of normal bacterial flora, 7. causing an astringent effect, 8. lowering the surface tension, 9. inducing a mucolytic effect, and 10. producing a proteolytic effect. **Vaginal suppositories** are used for the same purposes.

Certain applications of vaginal douches and suppositories may be more cosmetic than medicinal. Since the Food, Drug and Cosmetic Act specifically defines drugs as ". . . articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease," most of the uses for vaginal products are intended for drug use, rather than cosmetic application.

The classification of whether a product is a drug or cosmetic is dependent to a great extent on the nature and concentration of its ingredients. If an ingredient is present in a therapeutic concentration, even though no therapeutic claims are made, the product is classed as a drug. The FDA advisory panel that reviewed vaginal products concluded that uses 1-3 listed above are cosmetic rather than therapeutic claims. Therefore, vaginal products making only these claims are not required to undergo rigid scientific testing to prove their effectiveness.

When the term "deodorant" is used in conjunction with a douche product, the panel advised that it should be labeled to state the mode of action of the deodorant. A deodorant may be effective in reducing offensive odors because it: 1. removes vaginal secretions, seminal fluid, and contraceptive products from the vagina, 2. decreases the number of microorganisms that cause odors, or 3. masks offensive odors. The panel stated that OTC douche products do not actually destroy odors, but diminish a person's perception to them. So the designation "destroys odor" cannot be used on the labeling of these products.

Douching Techniques

Douching must be properly performed to maximize benefits and minimize risks of damage to the vaginal tissue. The vagina is lined with a mucous membrane that is highly susceptible to irritation. This membrane is actually an extension of the internal reproductive organs (i.e., uterus and fallopian tubes) and the abdominal cavity. The blood supply and lymphatic drainage system are shared by all these sites. Improper douching techniques and equipment may directly injure the vagina and introduce pathogenic microorganisms which can cause upper reproductive tract or abdominal infection. Some reproductive tract infections can result in sterility.

Currently there are no data to prove that routine douching is necessary for a normal, healthy woman. At the same time, there is no contraindication for the procedure in these women as long as they are not pregnant.

Some manufacturers advise against douching more frequently than twice a week. However, there are no definitive toxicity data that support this restriction. The frequency of douching does not appear to exert an adverse effect on the vaginal flora, cause vaginitis, or produce injury resulting from excessive dryness of the vaginal mucosa. The FDA advisory panel recommended against any restriction on the frequency of douching with OTC products.

Douching may cause pain, redness, swelling or itching within the vagina due to sensitivity to one or more of the product's ingredients. Vaginal or abdominal pain may also be indicative of improper use of douches, excessively hot solutions, or presence of a serious pathologic disorder in the pelvic region.

Some product labeling directs that the douche solution be instilled into the vagina with the vaginal opening occluded around the douche tip until a sensation of fullness is felt. There are numerous reports in the literature that warn against any procedure which occludes fluid outflow because the fluid may enter the uterus and fallopian tubes. Therefore, vaginal occlusion, or using a high intravaginal hydrostatic douching pressure (explained later) is potentially dangerous and should be discouraged. One report confirmed that 90% of women with salpingitis (inflammation of the fallopian tubes) or pelvic inflammatory disease douched frequently, whereas the condition appeared only half as often in women who did not douche.

Douching During Pregnancy. There are no data to substantiate the safety of douching during pregnancy. One survey of 510 pregnant women indicated that 12% of them continued to douche, with no harmful effects to mother or child.

However, the procedure is not without danger. During pregnancy, the uterine vasculature is increased. This large blood supply increases the woman's risk for vascular problems and systemic absorption of drugs. There are reports of fatal embolism following vaginal insufflation with powders and with air forcefully blown into the vagina. Soap and disinfectant solutions have also led to fatal intravascular hemolysis following attempts at self-induced abortion. Complications such as severe bleeding due to placental detachment, rupture of the chorionic membrane, or introduction of microorganisms have been recorded. As mentioned earlier, the fetus may also absorb chemicals which can produce deleterious effects.

The bottom line is that the risks of douching during pregnancy outweigh any possible benefits. Unless a physician specifically directs it, douching during this period should be avoided.

Ingredients Of OTC Douching Solutions

The FDA Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products reviewed the ingredients listed in Table 1 and assigned the classifications shown. A brief review of important findings follows.

Calcium and Sodium Propionate. The panel found these salts to be safe and effective in concentrations up to 20% for use in vaginal drug products claimed to relieve minor vaginal irritation. The panel also noted that propionates are safe and effective for physician-supervised treatment of infections caused by *Candida albicans*. But FDA responded that there was too much consumer uncertainty about the use of drug products to self-treat vaginal irritation that could be caused by this organism. Because calcium and sodium propionate salts have not previously been available except on prescription, they may not be marketed OTC until further studies are conducted to prove their safe use without direct physician supervision.

Potassium Sorbate. According to the advisory panel, potassium sorbate is safe and effective in concentrations of 1% to 3% for self-medication of minor vaginal irrita-

TABLE 1

FDA Classification of Active Ingredients of Vaginal Products

ACTIVE INGREDIENT	RELIEF OF MINOR IRRITATION	ALTERS pH	ASTRINGENT	LOWERS SURFACE TENSION AND MUCOLYTIC
Acetic acid		III(E)		III(E)
Alkyl aryl sulfonate				III(E)
Allantoin	III(E)			
Aloe Vera, stabilized	III(E)			
Alum			III(E)	
Benzalkonium chloride	III(S,E)			
Benzethonium chloride	III(S,E)			
Benzocaine	III(E)			
Boric acid	III(S,E)	III(S,E)	III(S,E)	III(S,E)
Boroglycerin	III(S,E)	III(S,E)	III(S,E)	III(S,E)
Calcium and sodium propionate*	I			
Citric acid		III(E)		
Docusate**				I
Edetate disodium	III(S,E)			
Edetate sodium	III(S,E)			
Hexachlorophene	II			
Lactic acid		III(E)		
Nonoxynol 9	III(E)			I
Octoxynol 9	III(E)			I
Oxyquinoline citrate	III(S,E)			
Oxyquinoline sulfate	III(S,E)			
Papain				III(E)
Phenol	II			
Phenolate	II			
Potassium sorbate*	I			
Povidone-iodine	I			
Sodium bicarbonate		III(E)		
Sodium borate	III(S,E)	III(S,E)	III(S,E)	III(S,E)
Sodium carbonate		III(S,E)		
Sodium lactate		III(E)		
Sodium lauryl sulfate				I
Sodium perborate	III(S,E)	III(S,E)	III(S,E)	III(S,E)
Sodium salicylate	II			
Sodium salicylic acid phenolate	II			
Tartaric acid		III(E)		
Zinc sulfate			III(E)	

*FDA will not allow marketing in OTC products at this time.
**Dioctyl sodium sulfosuccinate
Category I: safe and effective for OTC use; Category II: neither safe nor effective for OTC use; Category III: safety and/or effectiveness for OTC use not yet established
(E) — safety established, effectiveness in question
(S,E) - both safety and effectiveness need to be established

tion. It has demonstrated significant beneficial activity in treating various yeast infections. However, as with calcium and sodium propionates, FDA indicated that further studies on self-medication are needed.

Povidone-iodine. The panel concluded that povidone-iodine in a concentration of 0.15% to 0.3% is safe and effective to relieve minor vaginal irritation. Povidone-iodine has shown little local or systemic toxicity, and few sensitivity reactions. It can be absorbed and cause an increase in the serum protein-bound iodine level, but this has no significant effect on thyroid activity. However, several citations suggest possible mutagenic and carcinogenic actions. Povidone-iodine can modify the DNA structure of both bacterial and animal cells. But the few studies that report these actions are inconclusive. The panel, therefore, placed little significance on them. FDA agreed, but indicated it would continue to monitor safety reports on the drug for possible future action.

Anionic Surface Active Agents (docusate sodium, sodium lauryl sulfate). Used in concentrations of 0.002% and 0.02% respectively, docusate sodium and sodium lauryl sulfate are considered to be safe and effective for self use to produce a mucolytic action on vaginal fluids. These agents also lyse trichomonads and bacteria, and are used in prescription products for treating *Trichomonas vaginalis*. However, this claim cannot be made for OTC products since FDA believes that treatment of vaginal infections requires physician intervention.

Nonionic Surface Agents (nonoxynol 9 and octoxynol 9). These are safe and effective in concentrations of 0.0176% and 0.088% respectively for use in vaginal douches to produce a mucolytic action. In larger concentrations, nonoxynol 9 and octoxynol 9 are also safe and effective spermicides.

Unproven Ingredients And Claims

Treatment of Minor Irritations. The ingredients in Table 1 designated as "Category III" have been used in vaginal preparations for the specific actions shown. Some have been proven safe. Others have questionable safety. None has been proven effective for the specific indication(s) listed.

Manufacturers may conduct the clinical studies necessary to establish effectiveness of these ingredients until FDA promulgates its final "official" monograph on a particular drug group. If safety or effectiveness cannot be established by that time, these substances will not be permitted as active ingredients of OTC products, nor will their manufacturers be allowed to make the listed claims.

Allantoin has a long history of medical use. Its medicinal properties were discovered during World War I when it was noticed that maggot-infested wounds healed more quickly than noninfested wounds. Maggots produce a considerable amount of allantoin.

Allantoin has been used for years in many topical products and there are no specific toxicity problems documented. It has also been found by other FDA/OTC advisory panels to be safe for use on injured skin and on the oral mucosa.

Aloe is another interesting substance. Leaves of the aloe vera plant can be cut and squeezed to obtain an exudate. The exudate is not stable in air, and deteriorates within several hours. However, the commercially available forms are claimed by manufacturers to be stable.

The OTC panel reviewed more than 100 reports describing vaginal application of aloe vera. While no report cited specific toxicities, none of them substantiated proof of effectiveness either.

Quaternary ammonium compounds (benzalkonium Cl and benzethonium Cl) have been employed for a number of uses over the years. However, a critical assessment of the literature casts doubt on their safety and effectiveness for use in vaginal douche products.

There are no clinical studies dealing specifically with safety of using **benzocaine** on the vaginal mucosa. However, this local anesthetic has a long history of safe use on other mucous membranes. The advisory panel thereby concluded that benzocaine was also safe for vaginal use. While its effectiveness for alleviating vaginal irritation can be inferred from its use on other mucous membranes, such action will nevertheless require substantiation by studies using it on vaginal tissue.

Boron compounds (boric acid, boroglycerine, sodium borate, sodium perborate) have been instilled into various body cavities and applied topically for antiseptic uses for over a century. Boric acid has mild astringent action so it has also been used for its anti-inflammatory and antipruritic actions. There is insufficient evidence to establish that boron compounds are actually effective for these uses.

The safety of these compounds is also questionable. Reports of poisonings from boric acid resulting from ingestion, application of ointments and powder, and irrigation of closed body surfaces confirm the potential for toxicity. The review panel looked specifically for toxicity related to use in the vagina. In one review, three cases of boric acid intoxication following application were cited. But the studies were poorly conducted, and their outcomes were considered unreliable.

Edetate salts (edetate disodium, edetate sodium - EDTA) are thought to act on vaginal microorganisms by binding with calcium on their surface, thus interfering with metabolism and leading to their death. However, edetate salts also chelate other essential metal ions such as zinc from vaginal tissues. As a result, the panel felt they might be injurious. The panel suggested that edetate salts be limited to 4.4% concentration, and that they continue to be tested both for safety and effectiveness before a final ruling is made.

Nonoxynol 9 and octoxynol 9 are safe and effective mucolytics and spermicides, but there are insufficient data to show they are effective in relieving minor vaginal irritation. The drugs have been noted to reduce the number of pathogenic vaginal microorganisms such as *Trichomonas vaginalis*, but the data are inadequate to substantiate use in OTC products.

Oxyquinoline compounds (oxyquinoline citrate and sulfate) have been used for over 50 years to treat gonorrhea and other vaginal infections. The compounds form complexes with essential metal ions of microbes such as zinc and copper, and this is presumed to be their mechanism of action.

There have been no specific notations of adverse effects. However, animal studies have suggested possible carcinogenic activity. Because of a lack of specific data to show both safety and effectiveness, the panel recommended that further studies on oxyquinoline be initiated.

Agents that alter vaginal pH. A douching solution can change and maintain the pH of the vaginal fluids only as long as the solution remains inside the vagina. Within thirty minutes of cessation of douching with an acidic solution, the vaginal pH will return to its pre-douche level. In fact, it may become even more alkaline than before. This occurs because douching can remove glycogen, lactic acid, and other acids that normally maintain an acid environment.

Acetic acid, in a concentration of 4% to 6% when properly diluted, is safe when used in the vagina. Vinegar is approximately 5% acetic acid, and is also safe for intravaginal use when properly diluted (1.5 teaspoonfuls per quart of water). However, the data fail to show that it is effective in lowering the pH long enough to encourage growth of normal vaginal flora. Its use as a cleansing, "refreshing" douche is a cosmetic application. Therefore, this claim was not evaluated by the panel, nor is it affected by these regulations.

Other acids that are safe include **citric acid** (0.1% to 0.5%), **lactic acid** (0.4% to 1.3%), and **tartaric acid** (0.047%). However, none of these have yet been proven to be effective.

The alkaline substance, **sodium bicarbonate**, is safe in concentrations used in most douching solutions. The rationale for using it as a douche is presumably in its action to neutralize vaginal secretions. Such action is only temporary. Dilute solutions of baking soda labeled to produce a cleansing, "refreshing," or soothing effect are cosmetics rather than drugs.

Astringent Effects. Astringents are locally acting drugs that precipitate protein on the surface of cells. They cause constriction of mucous membranes, resulting in reduced local edema, inflammation, and exudation. Cellular permeability is altered, but the cell remains viable. **Alum** compounds in a concentration range of 0.037% to 0.06% and **zinc sulfate** in a concentration of 0.02% are safe. Neither has been proven effective. On the other hand, zinc sulfate in a concentration of 0.2% to 1.0% is an effective astringent, but has unproven safety for use in the vagina.

Alkyl aryl sulfonate, lactic acid, and **papain** are all safe for human use. None has undergone the testing needed to prove effectiveness in vaginally applied drug products.

Douching Equipment

The advisory panel reviewed douching equipment as well as drug products. It specifially warned against using any douching device with a nozzle that had a single, unshielded opening. This apparatus could force drugs or air into the uterus and fallopian tubes, and the abdominal cavity. The panel recommended that only nozzles with multiple openings be used. If a nozzle with a single opening is employed, the opening should be shielded so that the douche solution does not emerge in a steady, forceful stream. The panel also recommended that nozzles have a blunt end to minimize injuring the vaginal wall.

Some bulb-type syringes contain a device that occludes the vagina after insertion of the douching solution to prevent its drainage. The panel recommended against their use for the reasons expressed earlier.

Types of Douching Equipment. Two basic forms of douching equipment are available. The **douche bag** (fountain syringe or combination water bottle-fountain syringe) holds one to two quarts of fluid. It is supplied with tubing and a shut-off valve. The bag is suspended approximately two feet above the vagina and the fluid flow pressure is regulated by gravity. Increasing the distance of the bag above the vagina results in a

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greater hydrostatic pressure. The greatest height recommended is three feet.

The bag can also be used with a rectal tip to administer enemas. A rectal tip is shorter than a vaginal tip. It should not be used to administer douches because it has only a single, unshielded opening. The panel recommended that these nozzles be labeled for their respective uses to prevent consumer confusion, and it asked the industry to follow-up on this recommendation.

Bulb douche syringes hold eight to sixteen ounces of fluid. The nozzle is attached directly to the bulb and the flow rate is regulated by the amount of pressure exerted when squeezing he bulb. The currently marketed prepackaged disposable douche units are of this design, but hold hree to nine ounces of fluid.

The advisory panel raised a question concerning the volume of douche solution needed. Douche volume usually ranges from 250 to 2000 ml, with the average quantity approximately 1000 ml. The disposable units deliver much less, and this may not be a sufficient quantity of fluid to remove cellular material from the vagina. The panel believed that these smaller volumes were adequate for cosmetic purposes, but when a therapeutic claim is made, the manufacturer must prove that the volume is sufficient to achieve the desired effect.

Patient Advice

Whether or not routine douching is beneficial is controversial. Some gynecologists believe that a normal, healthy vagina cleanses itself. Others state that if douching is done properly, it will help promote healthy vaginal tissues. One important fact is that douching will not prevent pregnancy.

Another controversial topic concerns precoital douching to influence the sex of the offspring. Reports since the early 1970's have claimed he X-bearing sperm (female determinant) is more resistant to acid destruction than the smaller, Y-bearing (male determinant) sperm. Since the cervical mucous is most alkaline immediately prior to, or at the time of ovulation, the theory is that conception at this time is likely to result in a male offspring. Shortly after ovulation when the pH is more acidic, fertilization is more likely to result in a female offspring. If coitus were timed to coincide with periods more favorable to development of either male or female, the fetal sex might be influenced.

This viewpoint has been extended to employ acidic or alkaline (e.g., vinegar or sodium bicarbonate) douches precoitally to alter the pH and, therefore, facilitate the desired results. While some investigators have confirmed that the sex of the offspring can be affected in this manner, others have denied it. However, douching precoitally does not appear to detrimentally affect the health of the mother or fetus should conception occur.

Women should be sure they understand the correct procedure of douching. Table 2 provides specific points to aid in consumer counseling. Table 3 lists representative OTC douche products. One key point is that the proper method of douching is perhaps more important than the formula used. For example, physicians usually recommend douching in a reclined position, with the knees flexed and the hips slightly raised. It has been reported that only 30% of women follow this advice. When sitting or standing, only the outer one-third or one-fourth of the vagina will be reached by the douching fluid, even if the nozzle is fully inserted.

It should also be kept in mind that the symptoms caused by a wide variety of vaginal disorders are similar. While many conditions are mild and of no serious consequence, others can be severe. Whenever symptoms are severe or persistent, or worsen when a douche is being used, a physician should be consulted.

TABLE 2

Consumer Information on OTC Douche Products

- Do not use this product if you are pregnant, except on the advice of and under the supervision of a physician.
- If minor irritation has not improved after one week of use, or if you notice development of redness, itching, swelling or pain in or around the vagina after douching, consult a physician.
- This product is not intended to be used for birth control. It does not prevent pregnancy.
- Mix solution thoroughly according to manufacturer's directions just before use.
- Rinse all equipment well after each use. Keep it clean and dry between uses.
- Keep this product out of the reach of children.

TABLE 3

Representative OTC Douche Products

Product	Form
Betadine	Solution
Betadine Medicated	Disposable solution
Dismiss	Disposable solution
Femidine	Solution
Feminique	Disposable solution*
Gentle Spray	Powder
Massengill	Powder
Massengill	Disposable solution*
Massengill Concentrate	Solution
Massengill Medicated	Disposable solution
New Freshness	Disposable solution
Nylmerate II Concentrate	Solution
Sorbex	Granules
Stomaseptine	Powder
Summer's Eve	Disposable solution*
Summer's Eve Medicated	Disposable solution
Trichotine	Powder
Trichotine	Solution
Trichotine-D	Powder
Triva	Powder
Vagisec	Solution
Vanite	Powder
Zonite Concentrate	Solution

*available with different ingredients

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Elder Ed Talk III:

PRESCRIPTION DRUG PRICES, GENERIC DRUGS, AND PHARMACY SERVICES

by
Madeline Feinberg,
Director Elder-Health Program

This is the third in our series of Elder-Ed Community Talks being updated and reprinted from our June 1982 issue of *The Maryland Pharmacist*. Now, more than ever, this Association believes that practitioners need to maintain public visibility as consumers are demanding more information. It is pharmacy's responsibility to assure that pharmacists speak to issues which involve medications. Hence, we encourage you to get involved. Save these issues! And when you get a call from a local senior organization, just reach for these reprints. Or take the initiative yourself! We offer seven years of Elder-Health experience in dealing with consumer concerns. The most popular topics have been selected for reprinting and we offer free brochures (compliments of Parke-Davis Company) to distribute in conjunction with your presentations. Just call or write the Maryland Pharmaceutical Association.

Note to the pharmacist: Eighty-four percent of elderly pay for their prescription medications out-of-pocket. As pharmacists we are acutely sensitive to the ever rising and high costs of the medications which we dispense. Indeed, pharmacists "take it on the chin" for the medication bills of their older patients, who of course take more medications than any other population. We perceive that the subject of price is more important to our patients than any other pharmacy issue. Not true, when we speak to consumers in these group programs. The Elder Ed speakers report, as do many surveys on this issue including a recent AARP report, that older consumers rate service, information, and convenience as more important than price alone. See how your audience feels!

I. Introduction
  1. Introduce self
     (involve audience, invite participation)
  2. What is the most important thing you look for when you choose a pharmacy
     —price?
     —service?
     —convenience?
  3. Purpose of talk:
     —to discuss prescription drug prices . . . going up (but not as high as other goods and services)
     —saving money with generic drugs (can you? should you?)
     —pharmacy services—what you are "buying" when you pay for your prescription

Part 1. Prescription Drug Prices

I. Introduction

We all agree that prescription prices (and those of patent medicines as well) seem to be increasing all the time. It is true that the manufacturers have been raising prices several times during past years. However, prescription prices have not risen as fast as most goods and services listed on the Consumer Price Index.

Further, although it may seem that you are paying a lot of money for your medication, we suggest you figure out how much it costs for each day's worth of medication.

e.g. 100 tablets @ 20.00 (taking 2 tablets daily) costs 40¢ per day for medication.

II. How pharmacists price their medications
  —cost plus fee
  —percent markup
  —loss leaders

Loss leaders may be much cheaper for selected popular medicines, but may be more expensive for less commonly prescribed products.

III. Other ways to save money
  1. It's cheaper by the 100's
  2. But, always ask for a small quantity when starting a new medicine. It may not be right for you. If you do well on the medicine, ask the doctor to give you refills in quantities of 100. (This does not apply for all medications, such as tranquilizers or sleeping preparations.)
  3. Ask for senior citizen discount
  4. Or ask your pharmacist if there is a less expensive generic equivalent of your medication.

Part 2. Generic Drugs

I. What is a generic drug? (use pamphlet *Everything*

You Ever Wanted to Know About Generic Drugs)

1. Every drug has more than one name
   - —chemical name
   - —generic name
   - —brand name (give examples)
2. Drug patents: exclusive marketing rights for 17 years
   - —to defray costs of research and development of drug
   - —to cover testing of drug before it reaches the market
   - —to cover advertising costs of product

II. Are generic drugs as good as the brand name? Are they the same?

1. A generic drug can be substituted for the brand name when:
   - —the drug (i.e. active ingredient) is exactly the same, and
   - —the medicine has the same effect in the body as the brand name, and
   - —if it has the F.D.A. approval
2. Sometimes the generic drug looks different from the brand name:
   - —the color may be different
   - —the size and/or shape may be different
   - —it may look the same but have slightly different markings

   But, when your pharmacist substitutes the generic product for the brand name, it must satisfy the 3 conditions (above)

III. What should you do if you get a medicine which is different than your usual medication?

1. Do not take anything which looks different from your usual prescription medication without checking with the pharmacist:
   - —most pharmacists will notify you if they have dispensed the generic medication and will point out the different name on the label
   - —each state may have different laws regarding generic product substitution. Some states may require that the pharmacist obtain the doctor's permission first. Others encourage the pharmacist to substitute the equivalent drug and to notify the patient. Check with your pharmacist.

IV. How can you get a generic drug?

- —ask your doctor to prescribe a generic drug
- —ask your pharmacist to dispense the generic drug
- —sometimes you may have no choice. Your insurance company may require you to have the generic product. That is all they will pay for!

V. How does my pharmacist know if a generic drug is as good as the drug I am already taking.

1. Your pharmacist is the drug expert. He knows what drugs may and may not be substituted
2. The pharmacist you trust will only buy his generic drugs from a reputable manufacturer
3. Many large, well-known manufacturers now make generic drugs. For example Lederle, Parke-Davis, Smith, Kline & French manufacture many generic drugs.
4. Most important, the government must approve the generic drug before your pharmacist can purchase it. Many states now use a formulary system which lists only those manufacturers of approved generics

VI. Why do some doctors refuse to allow their patients to have a generic drug?

- —some prefer only the brand name because they have had good experience with it and do not wish to change

VII. Why do some pharmacies have mostly generic drugs, while other pharmacies have a small selection of generic drugs?

- —many high-volume prescription stores carry mostly generics whenever they can and offer a good price. In many cases, they may not even carry the brand name in stock
- —many smaller pharmacies may not carry a large inventory of generics (which duplicate the brand name), but instead, may have a larger variety of medicines—especially the less commonly prescribed medicines.

VIII. Can you really save 50% with generic drugs?

- —as a rule, probably not. You can save money. Shop around. Use the telephone. Ask how much it will cost to have your prescription filled. Be sure you know:
- —name of the medication
- —strength
- —quantity

Part 3. Pharmacy Services

(refer to pamphlet *How to Choose Your Pharmacy/Pharmacist*)

I. Special pharmacy services

1. patient profiles
   - —some states require by law
   - —explain what they are, how they are used
   - —explain how patient should use profiles

     shop at one pharmacy

     ask pharmacist to list your non-prescription medicines too

     ask pharmacist to help you keep your *Personal Medication Record Card* (available through Elder-Ed) up-to-date
2. Other (let audience lead discussion)

   delivery

   how long to fill the prescription

AND REMEMBER . . . If your pharmacist does not speak to you, it is your fault. If the pharmacist refuses to discuss your medications with you, take your business elsewhere!

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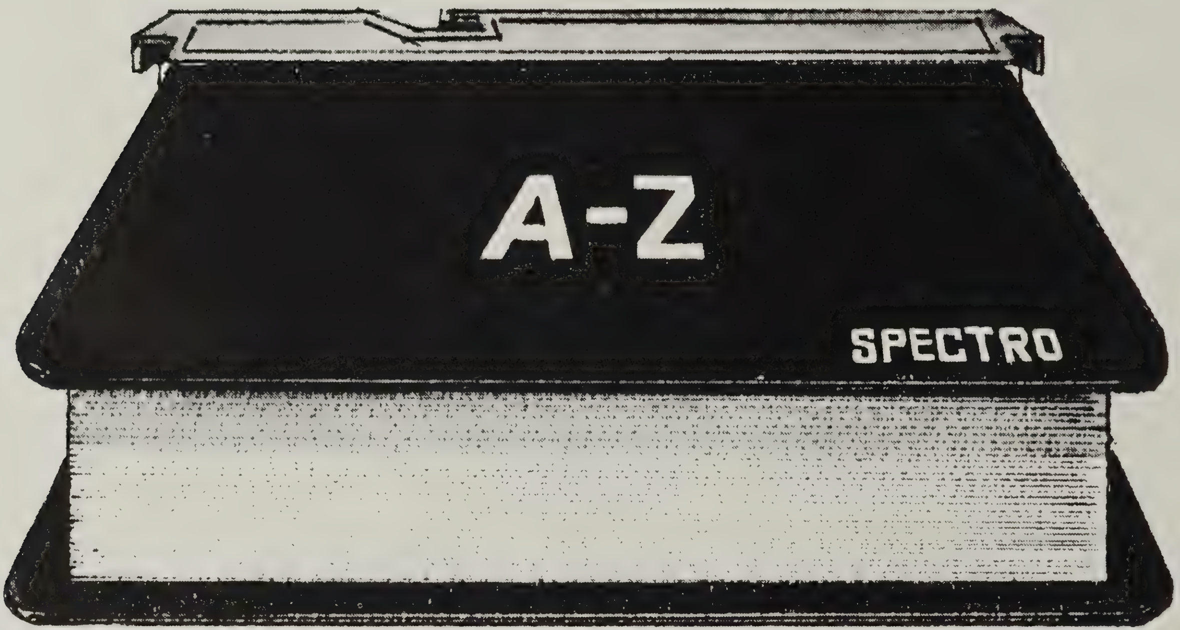

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Timely Topics

OSTEOPOROSIS: "THE SILENT EPIDEMIC"

Part II: Diagnosis and Treatment

by
Madeline Feinberg
Peter P. Lamy

Diagnosis—Osteoporosis is most commonly diagnosed when a fracture occurs, or less commonly, when discomfort or debility, resulting from changes in vertebral structure, is reported. Otherwise bone loss proceeds asymptomatically. Early detection of total bone loss and the rate of bone loss should reduce the incidence of fractures, but current diagnostic tests have only limited value in daily practice. Decrease in bone mass may simply be observed as "shrinking" or change in stature by the patient or her physician. By then preventive measures may be too late.

Several noninvasive procedures exist to evaluate bone density. Standard roentgenograms (X-rays) are most available, but are insensitive to bone changes which occur during the early stages of the disease. Approximately 30% loss of bone density must exist before osteoporotic changes can be detected on X-ray. Characteristic changes in spine and wrist which accompany the disease can be seen by x-ray and may be used to assist in the diagnosis. By then the disease is fairly progressed. A variety of other noninvasive techniques exists but vary in cost, availability, patient risk (to radiation dose), and sensitivity. The applicability of these tests for routine screening is yet to be determined.

Invasive procedures involve bone biopsy, usually from the iliac crest is one test. The procedure is considered safe and can provide a reliable diagnostic indication of bone disease, but skilled technicians and costly equipment are required, again with no wide availability.

Patients need to understand that if tests reveal bone loss, then the diagnosis of "osteoporosis" is made by excluding other possible causes of bone loss, such as endocrine or renal disorders, malabsorption syndromes or iatrogenic causes. This process of exclusion may involve batteries of other tests.

Treatment—"Cure" of osteoporosis is not a realistic goal of treatment. Once bone loss occurs, it cannot be replaced. Patients with established disease will be treated symptomatically for pain (primarily involves vertebral fractures), surgically (for hip fractures), and pharmacologically to prevent further bone loss and fracture. The National Institutes of Health Consensus Conference on Osteoporosis, April 1984, concluded that the mainstays of management of the disease are estrogen replacement therapy, calcium supplementation, vitamins and exercise regimens. Pharmacological management includes:

1. Estrogen—Carefully monitored estrogen replacement therapy for white women is recommended by conferees and other investigators to retard bone loss. Doses of conjugated estrogens 0.625 mg/day (or 25 ug mestranol, or 2 mg estradiol valerate) are considered protective against bone loss in the indicated population. (It has been shown to reduce by half the number of hip and forearm fractures in those who have taken estrogen for disease prevention.) Doses of 1.25 mg/day of conjugated estrogens have been recommended by some investigators if symptomatic vertebral fractures have occurred. However, it must be emphasized that the minimal effective dose for prevention, duration of treatment, use with progestogen, are among the issues that have not been determined by consensus. Most important, because of associated risk factors, the FDA has only approved estrogen replacement therapy as a treatment for osteoporosis, not for prevention.

Increased risk of endometrial cancer is associated with the use of postmenopausal estrogen. The magnitude of the risk is low. Morbidity and mortality from estrogen-associated tumors, when compared to the morbidity and mortality associated with clinically symptomatic osteoporosis is much less significant. Some researchers believe that alternate use of estrogen with progestogen may decrease risk.

No association has been found between post-menopausal estrogen use and the incidence of breast cancer. However, prior history of breast cancer or strong maternal family history may be a contraindication for estrogen replacement therapy.

On the other hand, estrogen may confer protective cardiovascular effects for the post-menopausal woman, but again, data is inconclusive.

2. Sodium fluoride—NaF has been used (1 mg/kg/d) to increase bone mass, however bone deformity, joint pain and severe gastrointestinal upset has occurred in more than half the patients on this regimen. The addition of calcium supplement has produced in some individuals a more normal bone structure, but nearly as many patients continue to experience side effects. Moreover, increased bone formation has not been associated with reduced incidence of fractures. This therapy continues to be studied under NIH protocol.

3. Vitamin D—Optimal calcium absorption requires the presence of normal amounts of Vitamin D. Supplementation of Vitamin D may only be indicated for those who do not receive adequate dietary intake or sunlight exposure, such as the homebound and bedbound patient. Care must be taken not to exceed normal requirements, as toxicity can readily result from high intake. Paradoxically, Vitamin D toxicity can enhance bone breakdown.

4. Zinc—Recent evidence linking zinc with normal bone metabolism has implicated this trace mineral in the pathogenesis of osteoporosis. The link, however, is not yet established.

5. Calcium—Adequate calcium intake is essential for normal bone maintenance. It is important to recognize that not only adequate intake, but absorption is a major factor in the availability of calcium for normal bone growth.

Factors influencing calcium absorption, calcium supplements, and recommendations for daily intake will be covered in detail in the next article of this column. Evaluation of products on the marketplace will be presented with cost factors considered.

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'Tween Scripts

By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.

—It's on the Label—

As every pharmacist knows, medicines are made with both "active" and "inactive" ingredients. Active ingredients produce the therapeutic effect. Inactive ingredients provide the "delivery system" and, among other necessary functions, they serve as flavors, colors, binders, emulsifiers and preservatives.

Inactive ingredients used in OTC medicines have long-established histories of safety; but, even so, a few people are sensitive to particular substances no matter how safe they are.

Now, manufacturers responsible for the vast majority of OTC medicines available to the American people are shipping products with new labeling which identifies *inactive* ingredients in the products, as well as *active* ingredients.

Today, virtually 100% of all relabeled OTC products are on retail shelves or moving through the distribution chain from manufacturers.

This action is the result of a voluntary program agreed to last year by members of the OTC industry in response to a Congressional inquiry on the subject.

Quantitative disclosure of *active* ingredients (FDA requires name only) was adopted by the OTC Industry in 1974 as another voluntary program.

Other voluntary initiatives adopted over the years by the OTC industry include the industry's code of advertising practices, its program of label "flagging" of formulary changes, bulk mail sampling practices and size and dose limits for children's aspirin.

A. H. Robins has played a leadership role in developing industry codes and guidelines to better serve the American consumer and those members of the health care team to whom the public looks for advice. All consumer-labeled packages of A. H. Robins products conform to the new guidelines.

Jake Miller

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Knapp Honored

The American Association of Colleges of Pharmacy's (AACP) Board of Directors has selected Professor David A. Knapp (University of Maryland School of Pharmacy) as the 1986 recipient of the Volwiler Research Award. Dr. Knapp was honored for his social science research within Pharmacy.

Knapp becomes the tenth winner of this prestigious Association award sponsored by Abbott Laboratories in honor of former Abbott President and Research Director, Dr. Ernest H. Volwiler. Presentation of the specially struck Volwiler gold medal and a $5,000 cash prize will be made at the AACP Annual Meeting in Toronto, Canada on July 16.

Nominations for the Volwiler Award are submitted by individual AACP members or by the chairs of the Association's various committees or academic sections. Selection committees representative of Pharmacy Education's multiple disciplines review each nominee's qualifications and submit their recommendations to the AACP Board of Directors for final determination of a winner.

The nomination of Dr. Knapp reads in part, "It is not at all an exaggeration to say that social and behavioral research in pharmacy would not have reached its present level without the models provided by Knapp's early pioneering work and the sustained quality of his research over a quarter century."

Having earned B.S., M.S. and Ph.D. degrees from Purdue University, Dr. Knapp has effectively addressed the central issues of practitioner performance relative to norms of appropriate care, qualitative and cost implications associated with prescribing patterns in both inpatient and ambulatory settings, the characteristics of drug use by the elderly, the impact of administrative controls utilized in the provision of drug benefits under health insurance programs, and the role of education in training pharmacists.

Editors Note: The following is the Legislative Alert sent to Maryland members of the American Association of Retired Persons regarding our bill, HB 1465, to regulate out-of-state mail order pharmacies. As a result of this "Alert," the Senate Finance Committee received many telephone calls from individuals worried about the effects of the bill on the cost of their medications. The bill was defeated in the Senate Committee after earlier receiving a unanimously positive vote in the House Committee.

URGENT! LEGISLATIVE ALERT

MARYLAND AARP MEMBERS

We need your help!!!!! Right now, the Maryland General Assembly is considering a bill which would force us to increase our prices substantially if it ever becomes law. HB. 1465 was introduced at the request of the Maryland association which represents independent retail pharmacists. These pharmacists want to use legislation to take **the competition that benefits you** out of the marketplace.

HB. 1465 would force our fully licensed and fully regulated Pennsylvania Retired Persons Pharmacy (and our new Virginia store, too) to seek a Maryland pharmacy license and become subject to duplicative, timeconsuming and burdensome additional regulations. If every state were to follow this example, we would become subject to additional regulations and even additional *state income taxes in every state* in the Union. Thousands of additional hours would have to be spent each year just keeping track of what all the different state Boards of Pharmacy were considering. The legal costs of appealing anti-competitive regulations around the country would skyrocket.

We would have to increase our prices in order to meet these new and unnecessary expenses and that's just what the independent pharmacists want.

HB. 1465 probably cannot be defeated in the House of Delegates but the Maryland Senate must consider the bill in the next 20 days. If you and any of your friends and neighbors who rely on the AARP Pharmacy Service would take the time to call or write your State Senators in Annapolis and urge them to defeat HB. 1465, **AS SOON AS YOU CAN,** we will be grateful. Please help us to keep your prices lower.

If you don't know who your State Senator is, call your local Registrar of Voters for the information. Your letters urging the Senators to defeat HB. 1465 can be sent to them in Annapolis.

The Honorable **John C. Doe**
Senate of Maryland
Senate Office Building
Annapolis, MD 21401
Dear Senator Doe:

If you want to call your Senator, the toll-free number is 800-492-7122. Call and leave your message. **Stop HB. 1465"**

Thank You.

THE AARP PHARMACY SERVICE

VETS PRACTICES ACT

In response to several inquiries from Pharmacists regarding the practice of Veterinary Medicine in Maryland, we are reprinting a portion of their Practices Act for the information of our members. Pharmacists may wish to keep this information for future reference. Questions can be directed to either the Veterinary Licensing Board or the Pharmacy Board.

§ 2-313. Prohibited acts.

A person may not:

(1) Practice veterinary medicine unless he is licensed, registered, and authorized to engage in the practice under the provisions of this subtitle;

(2) Practice veterinary medicine under a name other than the one on his license and registration, or induce any person to so practice in violation of this subtitle;

(3) Practice veterinary medicine unless his license and registration are displayed in his regularly established office and place of practice;

(4) Own, maintain, conduct, operate, or manage a veterinary office, veterinary dental office, veterinary hospital, or a dog, cat, or animal hospital, unless (i) he is a licensed veterinarian, or (ii) the office or hospital is under the direct supervision and control of a licensed and registered veterinarian and a licensed or registered veterinarian is employed in the office or hospital;

(5) Advertise any veterinary office, veterinary dental office, veterinary hospital, or a dog, cat, or animal hospital except in accordance with the rules and regulations of the Board;

(6) Practice veterinary medicine and sell or dispense any medication, which is not in the original manufacturer's container labeled with the information required below, for use by a household pet unless he affixes to the container in which the medication is sold or dispensed, a label clearly showing the brand, generic or chemical name and strength, if indicated, of the medication, the type of animal for whom designated and the owner's last name. However, this provision does not apply to the dispensing of any medication of any kind for use in the treatment, care or cure of farm animals, poultry, fowl, or other animals, used in the furtherance of farming activities;

(7) Advertise as a Board registered veterinary technician unless registered with the Board as required by this subtitle; or

(8) Practice as a veterinary technician unless employed by a veterinary practitioner.

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Program At A Glance

Sunday June 22	Registration Open at **12:00 Noon to 5:00 p.m.** (rooms available at 3:00 p.m.) Wine an Cheese at registration desk. Tennis Golf, Swimming, Special Gifts and ''Goodie Bags.' Programs and tickets available. **9:00 p.m.** Welcoming Cocktail Party Sponsored by th Drug House.
Monday June 23	**8:00 a.m.** Record number of Exhibits Open. Coffee and Donuts **9:00 a.m.** C.E. Program. Top Nutritionists in the Country to address — Nutrition and th Elderly * Trace Minerals * Vitamins * Panel Discussion and Question and Answer **Watch for Details on this outstanding C.E. Program** **10:00 a.m.** LAMPA Brunch and Fashion Show **6:30 p.m.** Crabfeast and Chicken at Berlin Fire Hall — Square Dancing
Tuesday June 24	**8:00 a.m.** Exhibits open. Coffee and Donuts **9:00 a.m.** Opening General Session House of Delegates **8:00 p.m.** Cocktail Party and Hawaiian Luau
Wednesday June 25	**9:00 a.m.** Second business session of the House of Delegates. Resolutions, Installation o Officers, Committee Reports. **6:00 p.m.** Cocktail Party **7:00 p.m.** Annual MPhA Banquet — Awards and Prizes
Thursday June 26	**9:30 a.m.** Special C.E. Program — Simon Solomon Seminar by William Skinner, P.D., J.D

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Pharmacy Around The World, Part Two

by Grady Dale, Jr., Ed.D.
Assistant Dean for Student Affairs
University of Maryland School of Pharmacy

(In the April, 1985 issue of The Maryland Pharmacist, Dr. Grady Dale, Assistant Dean for Student Affairs, University of Maryland School of Pharmacy, reported on his visit to ''STADT-APOTHEKE (Town Pharmacy)'' in Metzingen, Federal Republic of Germany. This is his second report on pharmacies outside the United States.)

There's more to Mexico than sunny beaches, smiling senoritas, and afternoon siestas. For the modern pharmacist Mexico is also a land of unparalled freedom, opportunity, and community status.

Last December my wife, Helen, and I spent two weeks in Mexico, one week on an isolated Pacific beach, and the other in that most cosmopolitan of cities, Guadalajara, in the prosperous state of Jalisco. We visited with pharmacists in Ameria, the closest town to our beach resort, and also with an urban pharmacist in the ultra-modern Chapalita section of Guadalajara. We learned that pharmacists in Mexico have the best of both worlds, traditional and up-to-date.

In Ameria, where the average temperature in December is 95 degrees, and the local people close up shop during the heat of the midday sun, we came to town on the local bus from Cuyutlan (for a cost of 100 pesos, approximately twenty-five cents each) in search of the pain remedy suggested by the hotel proprietress for Helen, suffering from neck pains after lugging an enormous shoulder bag. ''Just ask the pharmacist for PRODOLINA'', she had advised.

Getting off the bus after the half-hour ride in sweltering midday sun, we were engulfed by waves of heat so overpowering that we felt our knees buckle, and the sweat beneath our straw sombreros running down and meeting under our chins. We ducked under the nearest awning, discovered it was the doorway to an inviting little ''fonda'' where perhaps five or six people were sitting at tables drinking delicious-looking flavored and colored water over chunks of melting ice. Nearly melting ourselves, I said, ''Let's try one of those'', and motioned to the smiling waitress who was busily dipping up glasses of the liquid from several five-gallon clear jars. Helen, who has spent some time in Mexico, suggested mildly, ''Let's try FANTA, instead.'' We sat at a tiny, oil-cloth covered table and watched the people watching us, until we finished our drinks, returned the bottles, paid, tipped, and ventured outside into the now-deserted main street. At the next corner we saw the familiar ''FARMACIA'' lettering on a not-too-clean front window, and stepped inside to a cool, well-stocked, modern pharmacy. The pharmacist was dressed casually in a white jacket and light slacks. He looked up from his ''DICCIONARIO DE ESPECIALIADES FARMACEUTICAS'', the equivalent of our Physician's Desk Reference, and greeted us warmly. (We were a rare sight in this part of Mexico. In fact, at the hotel we were registered simply as Dos Americanos.) I asked in my limited Spanish for ''PRODOLINA, POR FAVOR, SENOR.'' He replied, ''Si, Prodolina. Cuantos, Senor?''. ''Un Pacquete,'' I mumbled, hesitantly. He smiled, and went to an aisle where long rows of small drawers were stacked from waist high to about ten feet from the floor, and reached into a tall drawer. He looked at me and asked again, ''Uno?'', and I nodded ''yes''. He brought out one small box, set it on the counter and began writing a sales slip for one hundred forty pesos plus fourteen pesos tax. (This is the equivalent of about forty five cents in U.S. currency). I paid, took the package, and we left the store, heading back to the shady refuge of the little restaurant to wait for our bus. As we sat in the restaurant I took the PRODOLINA from the bag and started to read the list of ingredients. ''I don't know about Mexico,'' I said to Helen, ''but I can tell by reading this box that this is a controlled substance in the United States. I think you're going to have to get along without taking this for your neck pains''. This innocent box of ten individually-foil wrapped tablets was percodian, and the dosage was considerably more than what we needed for Helen's discomfort.

There is a sizeable American Colony in Guadalajara, Mexico's second city, at 5,000 feet with an average year-round temperature of 73 degrees. Approximately 25,000 in this city of 9 million. One third are medical students attending the Autonoma University. The rest are either long or short-term residents, or simply ''snow birds'' escaping the cold northern climes. Many live in Colonia Chapalita, a community of flower-laden boulevards, spacious homes, new apartments, squeaky-clean supermarkets, laundromats, bookstores, and ''farmacias''.

We visited the FARMACIA COLONIAL in a neat, mini-mall across from a beautiful small park where music is played from an ornate gazebo on Sunday afternoons.

Pharmacist Hoyos and Grady Dale

Señor Hoyos and assistant in Guadalajara "Farmacia Colonial"

Senor Gonzalo Hoyos Sanchez has owned the Farmacia Colonial since 1970. He has worked in pharmacy since he was twelve years old, beginning 40 years ago in a small town, San Mateo de Tenca near Toluca, not far from Mexico D.F.. "The lake was drained for Mexico City, and when the lake, Laguna de Lerma, was drained, the city was no more", he explained in his halting, but very clear, English. "My uncle was a pharmacist. He taught me how to make the preparations. All my life was in or near drugstores," he continued. Senor Hoyos was born in Pachuca, in the state of Hidalgo, the first city in the production of silver in Mexico. He attended the "secondario and preparatrio" schools, and studied medicine. He began making compounds in secondary school at age 12. After 3 years in the University of Mexico Medical School, he had mastered biology, chemistry, mathematics, and inorganic chemistry. He worked for Parke-Davis Company for 21 years, and then opened his own pharmacy.

I asked Senor Hoyos some specific questions about the profession of pharmacy in Mexico:

1. Q. "What are the laws governing pharmacy in Mexico"?
   A. Pharmacist must be trained, and must pass state and federal examinations. The training required includes courses in organic chemistry, beginning chemistry, inorganic chemistry, biology, mathematics, and health. The State and Federal Health departments in each state prepare and administer joint examinations. There is no separate school for pharmacy training because the courses are given in the university. In addition to the license a pharmacist must also have experience in a pharmacy. An additional requirement; inspectors for Health Department come once a year to examine records on prescription drugs. They are very strict about examining these records.
2. Q. "What types of drugs require a prescription"?
   A. Diet pills, sleeping pills, tranquilizers, such as valium, and antianxiety agents such as ativan.
3. Q. "What types of medicines are available to the consumer without a prescription, over the counter?"
   A. Any drug which does not require a prescription is available over the counter. This includes capsules, tablets, injections, liquid suspension, and other medications.
4. Q. "Does this include medicines such as penicillin, insulin, and percodan"?
   A. Yes. These are available over the counter, without a prescription.
5. Q. "Why is it so easy for people to get these medicines without a prescription"?
   A. Many people are too poor to see a doctor. They come to the pharmacist and ask us what to take. We give them the medicine they need and they save money.
6. Q. "What about narcotics"?
   A. Prescriptions for narcotics are strictly controlled. There are very few physicians, and very few pharmacists authorized to prescribe or to dispense narcotics. For example, only "First Class" pharmacies are allowed to fill prescriptions for narcotics. And only a few doctors have the authority to write prescriptions for morphine or other narcotics. In a city the size of Guadalajara only a few pharmacy stores are First Class, and allowed to fill narcotic prescriptions. (First Class is a designation, usually given to one store in a chain per city, or to a private pharmacy that meets certain rigorous standards set down by the health department. The Farmacia Colonial is a First Class Pharmacy.)

7. Q. "What is the source of your compounds, and how are they dispensed"?
   A. All the major international pharmaceutical companies have operations in Mexico . . . Bayer, Ciba, Geigy, Imperial Chemical Incorporated. The Transnational Companies sell 85% of all the drugs used in Mexico. Everything sold is prepacked for hygiene and standardization. Prices are governed by the State. Most people can afford to pay for the common medicines, which are manufactured here with imported ingredients. Service is very good. I make three orders a day from wholesale distributors, and get next day delivery. This helps me save on inventory costs.
8. Q. "What is the official designation for pharmacists once they earn their license"?
   A. They are just called pharmacist.
9. Q. "What is the ratio of men to women in pharmacy"?
   A. It is are about 10%. Pharmacy is opening up to women, but most pharmacists are still men.
10. Q. "What kinds of associations for pharmacists are there in Mexico? Is there an official publication for pharmacist"?
   A. There is no association of pharmacists, just for pharmaceutical companies. There is no pharmacy publication.
11. Q. "Why do people go into pharmacy as a profession"?
   A. In Mexico, where we have so many poor people, a pharmacist can provide important services to the people. We are not supposed to prescribe medicine, but the government knows the people need help, and that they will come to us because they can't afford a doctor. Because we are located in the neighborhoods everywhere, and have long hours, people come to us when they are in many kinds of trouble. They know they can trust us to help them, and to treat them fairly. It is a very rewarding way to spend your life . . . helping people.
12. Q. "What is your biggest seller"?
   A. Maalox Plus is my biggest seller. This is a new situation. When I started in pharmacy we didn't have anything such as Maalox. Now everybody has stomach problems. It can't be the poverty, because things are better nowadays. I think it is the stress and tension that makes everybody sick. I think it is a sign of the times.

(Senor Hoyas and his wife, Sra. Maria del Carmen Garrido de Hoyas are the parents of 4 sons, Dr. Jorge Hoyos Garrido, a dentist, Guillermo Hoyos Garrido, a Certified Public Accountant, Ricardo Hoyos Garrido, in telecommunications work, and Luis Hoyos Garrido, an Urban Planner who earned his Masters In Urban Design from Harvard. They also have a daughter, Maria Carmen, who is presently a student of Industrial Arts at the Autonoma University in Guadalajara.)

Mexico, our neighbor to the south, is a charming land for vacations in the sun. After you leave the beaches however, and venture into the cities where people live, work, and rear their families, much the same as people anywhere, you'll find that the community pharmacist fills an important role. The profession provides opportunity for a prosperous life, with security and status while rendering a valuable service that is sorely needed. We found, in Mexico as in Germany, that "We have much to learn from each other."

From Skyway News, "Men and Women Together", February 27, 1986

Dear Janice:

I work as a pharmacist in a family-owned business. The husband is a pharmacist and he runs the store. His wife handles all the bookkeeping and I think she handles him too. The problem is that she is so controlling and very demanding. I feel like I have been taken for granted a lot. He leaves town often and dumps all the responsibility on my shoulders. I complain to him about my salary and my work load and the next thing I know *she* is on my back. Just who am I working for and why is it he seems to take out his frustrations on me? I feel stuck in the middle and would like out, but fear the loss of my job.

Signed, Who's the Boss Anyway

Dear Who's the Boss Anyway:

As you already know, a family-owned business is just that, family owned. He may be the professional, but she obviously has a say in how things are run. Now it may appear that he resents her controlling nature and takes his anger out on you. It probably will not work for you to confront the situation directly, but if you feel mistreated you can certainly demand respect. If he is in a bad mood, you can let him know that you will not accept his anger being directed at you. Take care of yourself. If you are unhappy, let it be known. If your desires are unappreciated, then you might have to accept that this is life in this family. If you are afraid of losing your job, that can inhibit your speaking up for yourself. Try not to be afraid, because those fears can be your own worse enemies.

The Baltimore Metropolitan Pharmaceutical Association's Annual Banquet was held March 9th. George C. Voxakis (left), President of BMPA, presented Nathaniel Futeral (right), with the Past President's Plaque.

Howard Schiff, President-elect of the BMPA, served as Master of Ceremonies for the affair which was held in Baltimore at the Blue Crest North.

Gary McNamara (left) from the Drug House receives the Honorary President's Award from BMPA President George C. Voxakis (right).

The NARD Home Health Care Seminar was held in Baltimore March 6–9. Many Marylanders were featured on the program. NARD President Joseph Schutte (left) introduces a panel discussion. Shown are: (left to right) Madeline Feinberg, MPhA President and panel moderator, Matthew Shimoda, Mark Abrams and Allan Ginsberg.

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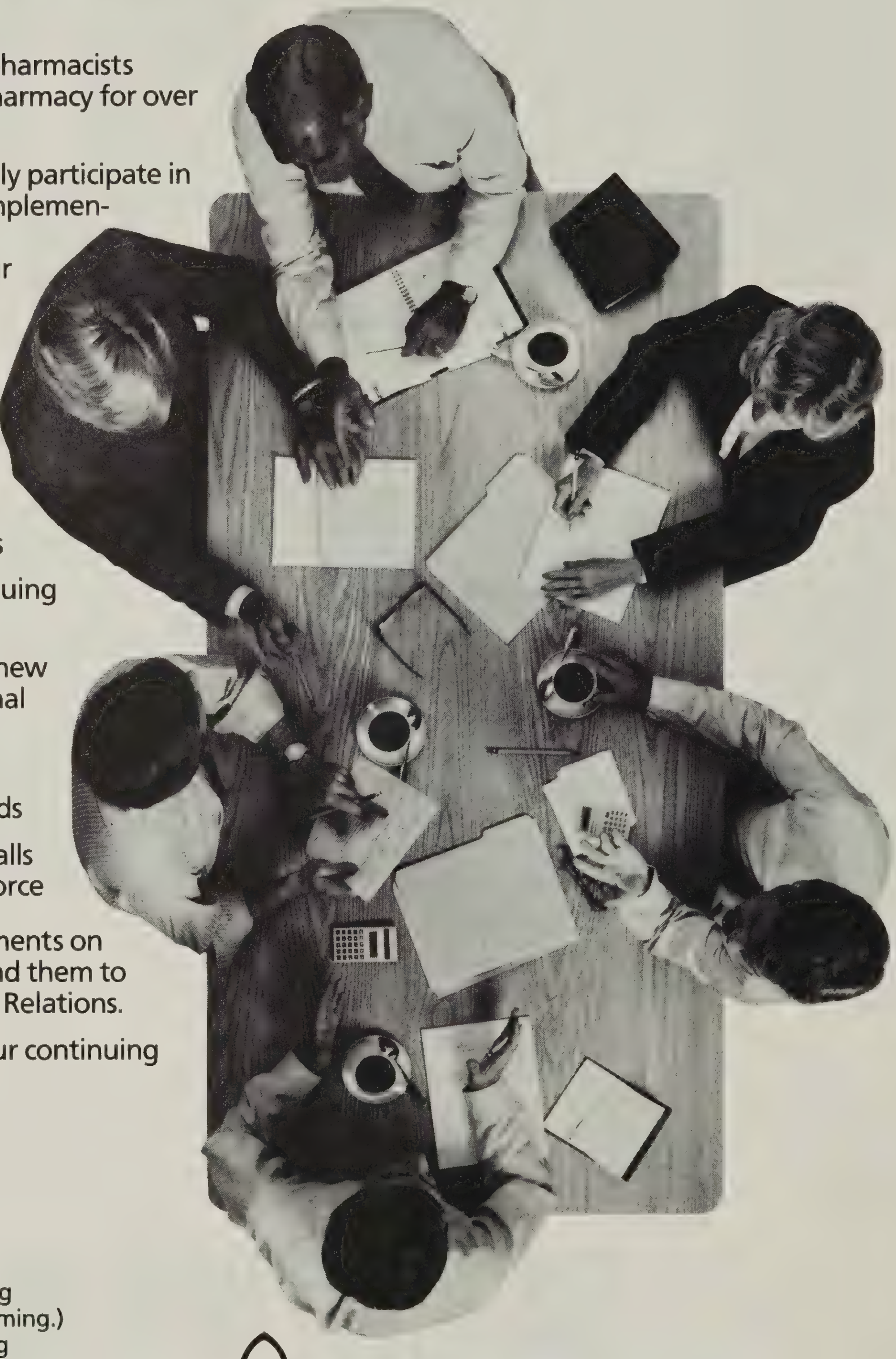

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calendar

May 2–3—Grass Roots 21, Seminar, Arlington, Va
May 22—Alumni Association Graduation Banquet
May 18—CECC "The Role of the Pharmacist in Diabetic Patient" Seminar
May 23—School of Pharmacy Commencement Exercises
June 20–22—MSHP Annual Seminar Ocean City
June 22–26—MPhA CONVENTION AT THE ENLARGED SHERATON HOTEL OCEAN CITY, MD.

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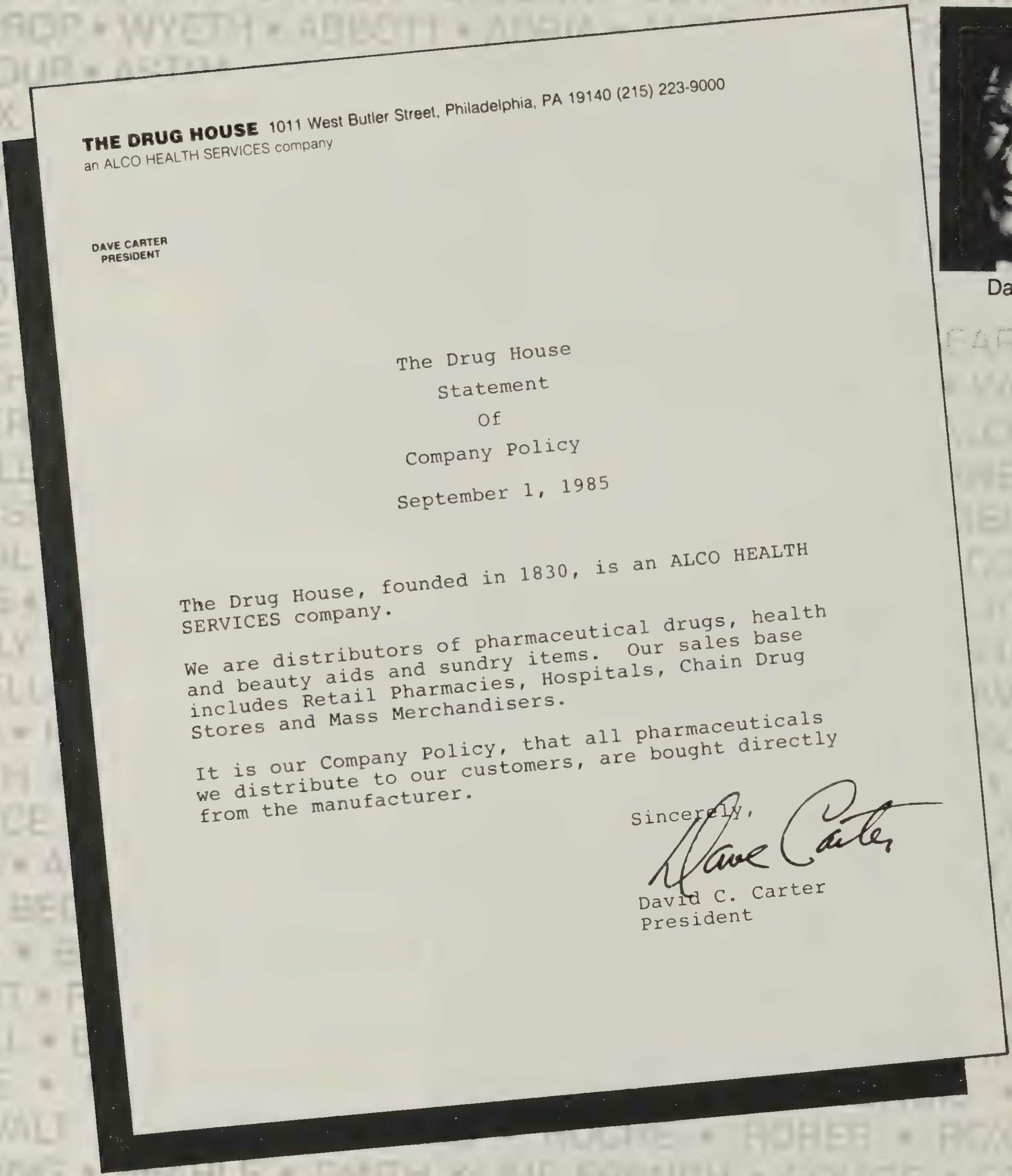

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THE
MARYLAND
PHARMACIST
Official Journal of
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Pharmaceutical
Association

June, 1986
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1986 Legislature Wrap-up

OTC Vaginal Contraceptives

— Thomas A. Gossel
— J. Richard Wuest

Elder Ed Talk IV: Selecting the Right OTC Medicines

— Madeline Feinberg
— Peter P. Lamy

Factors Affecting Dissolution and Absorption of Calcium Supplements

— Ralph F. Shangraw

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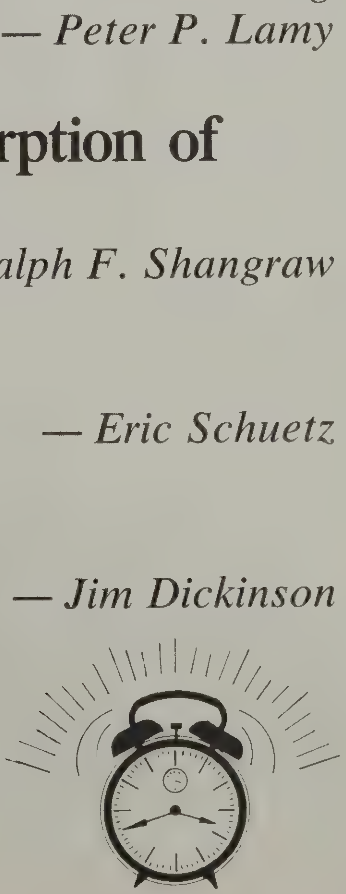
— Eric Schuetz

Mail Order: A Disaster Waiteth

— Jim Dickinson

Timely Topics — Osteoporosis



THE MARYLAND PHARMACIST

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President's Message

Pharmacist Prescribing

Hot on the heels of our efforts to restrict physician dispensing of pharmaceuticals, comes a "new" issue, enactment of the Florida law allowing pharmacists to prescribe certain categories of drugs. The television media called MPhA to find out where pharmacists stand on this issue. Will we ask for the right to prescribe while restricting the physician's right to dispense?

Where indeed do we stand? The Florida law authorizes prescribing from a limited formulary which has created a third class, or pharmacist-legend category of drugs. Do pharmacists in Maryland want both the responsibility and liability entailed in prescribing drugs?

It has been predicted that within 30 years, half the prescription drugs we have today will be over the counter. These will probably include cimetidine, propranolol, hydrochlorothiazide among others, drugs that we know to have the potential for serious adverse effects in certain at-risk patients. Do we want to put these drugs up for grabs on aisle 4B or behind the counter, restricted to "pharmacist-only" sale?

Pharmacists are trained to select the appropriate drug for a given patient and indication and to monitor for therapeutic efficacy and toxicity. Therefore I believe we have the expertise and the *obligation* as professionals to be "for" a pharmacist-legend category of drugs, particularly in view of the RX to OTC switching which is upon us now. Some may oppose this position . . . the Proprietary Association, third party payors, unions, employers, physicians, consumers, perhaps even some pharmacists and their employers who view their pharmacist merely as a dispensing agent.

I believe we have to act now if we want to advocate a pharmacist-legend category tomorrow. We need to get out from behind the counter, take a more active role in helping patients select non-prescription medications today. We need to counsel patients on their prescription medications. We need to work more closely with physicians in helping to monitor patient response and adherence to prescribed regimens. And most important, we need to let the "opposition" know how well we do these tasks, so that tomorrow we can enlist their support in maintaining certain categories of drugs under the supervision of a health care professional—the pharmacist!

Madeline Feinberg,
PRESIDENT

Editor's Note: In this issue of the *Maryland Pharmacist* you will find several advertisements for purchase of the publications USP-NF, USP-DI and "About Your Medicines." Prices for all three are scheduled to rise on July 1, 1986. However, through a special arrangement, we are able to offer these publications to you at the current prices if orders are received using the forms in this Journal before September 1, 1986. Beat the price increase by ordering now! Take advantage of this special membership arrangement.

Lobbying for Pharmacists

1986 Legislature Wrap-up

The work of the Maryland Pharmaceutical Association in the area of government relations is perhaps the most vital function of the Association on behalf of all pharmacists; whether they are members or not. It is true, unfortunately, that even non-members of the Association benefit whenever the Association is successful in its lobbying efforts to the extent that the practice of pharmacy is enhanced for all pharmacists. The Association in effect represents all pharmacists when testimony is presented before legislative committees, when interviews are conducted with the news media, and when position papers are provided to important government agencies.

The Association works in cooperation with a number of other lobbying groups such as the Medical Society, the Dental Association, the Nurses Association and several other allied health care professions. The MPhA also works with manufacturing interests, the Association of Chain Drug Stores, insurance companies, proprietary and business interests and others. As the Association begins to formulate a position on specific legislative issues, it coordinates its views and testimony with several other groups within the profession of pharmacy such as the Board of Pharmacy, the School of Pharmacy, the Maryland Society of Hospital Pharmacists, the Maryland Chapter of the American Society of Consulting Pharmacists, the Pharmacy Guild and others to ensure that the voice of Pharmacy can be presented in as unified fashion as possible.

The responsibility for legislative activity is conducted by the Legislative Committee, under the Chair of Paul Miller. Working with the Executive Director, David Banta, who is also the Association's registered lobbyist, the Committee gets its general policy direction from appropriate resolutions from the House of Delegates. Early each Fall, the Committee suggests a legislative platform of positions on issues and proposed bills which is then subsequently ratified by the Board of Trustees. The Committee monitors the legislative process while the General Assembly is in session and makes decisions regarding revised policy as the need develops and situations change. Banta monitors the activity of the legislature on a daily basis during the session. He develops, coordinates and presents testimony on the bills that are heard before legislative committees, including the presentation of position papers when necessary. Occasionally, pharmacists, usually from the Legislative Committee, are called upon to provide expert testimony on certain bills of a technical nature. Certain larger issues will call for a major showing of pharmacy support or opposition in the form of multiple witnesses or an organized telephone and letter campaign. These activities are coordinated by the Legislative Committee.

The results of the work of the Legislative Committee is reported back to the membership in the Newsletter during the session and as a Committee report at the Annual Convention. Over the past several years, the Association has been very successful in full-filling its legislative goals while utilizing a maximum efficiency in expenditure of Association resources. This past year was very productive for the Committee. Of course the Governor must sign into law each of the bills which passed the legislative process and they will not take effect until July 1, 1986 in most cases. Below is a summary of the major bills which were worked on and followed by the Association this year.

Physician Dispensing

SB 830

(b) This title does not prohibit:

(1) A licensed veterinarian from personally preparing and dispensing the veterinarian's prescriptions;

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

(I) The dentist, physician, or podiatrist:

1. Has applied to the Board of Licensure in this state which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs by the dentist, physician, or podiatrist is in the public interest; and

3. Has recieved the written approval of that board to dispense prescription drugs;

(II) The person for whom the drugs are prescribed is a patient of the prescribing dentist, physician or podiatrist;

(III) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(IV) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of § 12-510 of this title; and

2. Records the dispensing of the prescription drug on the patient's chart or as otherwise permitted or required by the board that licensed the dentist, physician, or podiatrist.

(3) A hospital-based clinic from dispensing prescriptions to its patients.

(c) This title does not prohibit:

(1) A licensed verterinarian from personally dispensing a drug sample to a patient of the veterinarian; or

(2) A licensed dentist, licensed physician, or licensed podiatrist from personally dispensing a drug sample to a patient of the licensed dentist, licensed physician, or licensed podiatrist if:

(I) The sample complies with the labeling requirements of § 12-510 of this title:

(II) No charge is made for the sample; and

(III) The authorized prescriber enters an appropriate record in the patient's chart.

(D) (1) This title does not prohibit a dentist, physician, or podiatrist from administering a prescription drug in the course of treating a patient.

(2) For the purposes of paragraph (1) of this subsection, "administering" means the direct introduction of a single dosage of a drug at a given time, whether by injection or other means, and whether in liquid, tablet, capsule, or other form.

(E) (1) This title does not prohibit a dentist, physician, or podiatrist from personally dispensing a starter dosage of a prescription drug to a patient of the dentist, physician, or podiatrist.

(2) For the purposes of paragraph (1) of this subsection, "starter dosage" has the meaning commonly accepted in dentistry, medicine, or podiatry, unless defined otherwise by regulation of the board that licensed the dentist, physician, or podiatrist.

(F) This title does not prohibit a dentist, physician, or podiatrist from dispensing a prescription drug in the course of treating a patient:

(1) At a medical facility or clinic that specializes in the treatment of medical cases reimbursable through workmen's compensation insurance:

(2) At a medical facility or clinic that is operated on a nonprofit basis:

The Association retained Mr. Judson Garrett of the law firm of Tydings and Rosenberg as a professional legislative representative to assist with the 1986 lobbying effort. It was with his invaluable assistance that the Association succeeded in the passage of several important bills.

(3) At a health center that operates on a campus of an institution of higher education: or

(4) At a public health facility, a medical facility under contract with a state or local health department, or a facility funded with public funds.

Dental, Medical or Podiatry Boards

(a) (1) In addition to the powers set forth elsewhere in this title, the Board may:

(I) Adopt rules and regulations to:

1. Carry out the provisions of this title;

2. Regulate the performance of acupuncture, but only to the extent authorized by § 14-605 of this title;

(II) After consulting with the State Board of Pharmacy, adopt rules and regulations regarding the dispensing of prescription drugs by a licensed physician; and

(III) Subject to the Administrative Procedure Act, deny a license to an applicant for any of the reasons that are grounds for action under § 14-504 of this title.

(2) The Commission on Receipt of a written and signed complaint may investigate an alleged violation of this title.

AND BE IT FURTHER ENACTED, That on January 1, 1988 and on January 1, 1989 the State Board of Medical Examiners and the State Board of Pharmacy shall report to the standing committees of the General Assembly with primary jurisdiction over this Act on the economic and social impact of this Act on physicians, pharmacies, and consumers.

AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 1987.

World class advice for your every day problems.

More than 50,000 pharmacists know these men and use their wisdom to solve everyday problems. Dave Schmidt and Harles Cone, Ph.D., gave them a better understanding of human nature and improved their ability to communicate. And many have profited from the good dollar sense of Allan Hurst and his lectures on financial planning, cash flow and store management. We're proud to have brought their Professional Development programs to your association meetings and conventions during the past 12 years. We hope they made your world better.

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Rehabilitation Committee

SB 831

(A) In this section "Pharmacist Rehabilitation Committee" means a committee that:

(1) Is within one of the categories described in subsection (B) of this section; and

(2) Performs any of the functions listed in subsection (C) of this section.

(B) For purposes of this section, a pharmacist rehabilitation committee is:

(1) A committee of the Maryland Pharmaceutical Association;

(2) The Maryland Society of Hospital Pharmacists; or

(3) Any other professional society or association that:

(I) Is recognized by the Board; and

(II) is composed of pharmacists.

(C) For purposes of this section, a pharmacist rehabilitation committee evaluates and provides assistance to any pharmacist in need of treatment and rehabilitation for alcoholism, drug abuse, chemical dependency, or other physical, emotional, or mental condition.

(D) (1) Except as otherwise provided in this section, the proceedings, records, and files of a pharmacist rehabilitation committee are not discoverable and are not admissible in evidence in any civil action arising out of matters that are being or have been reviewed and evaluated by the pharmacist rehabilitation committee.

(2) Paragraph (1) of this subsection does not apply to any record or document that is considered by the pharmacist rehabilitation committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial.

(3) For purposes of this subsection, civil action does not include a proceeding before the Board or judicial review of a proceeding before the Board.

(E) A person who acts in good faith and within the scope of jurisdiction of a pharmacist rehabilitation committee is not civilly liable for any action as a member of the pharmacist rehabilitation committee or for giving information to, participating in, or contributing to the function of the pharmacist rehabilitation committee.

Prescriptions

HB 1476

(b) (1) A prescription may be written or oral. However, a pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

(2) A prescription for a controlled dangerous substance within the meaning of article 27 of the code may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance.

(3) When a prescription is written, a separate prescription form is required for each controlled dangerous substance. If a pharmacist is otherwise satisfied that a prescription is valid the pharmacist may fill the prescription if the pharmacist promptly writes out and files a prescription for each substance and also files the original prescription.

Other Bills

HB 659 passed and requires that any profit or nonprofit insurer or health service plan that issues or delivers any individual or group policy, contract or certificate within this State to reimburse health care providers within 30 days of the proper filing of a claim or be responsible for the payment of interest at the rate of one and one half percent per month on the amount until it is paid. The bill does not apply to claims where there is a good faith dispute regarding legitimacy of the claim or the appropriate amount of reimbursement. If signed by the Governor the bill would take effect on July 1, 1986 and the Association considers it to be a major victory in the battle for prompt payment of bona fide third party claims.

HB 1475 passed and provides that a prescriber may not use a signature stamp in place of the actual signature.

As mentioned in the May issue of the *Maryland Pharmacist,* the bill to regulate out of state pharmacies — HB 1465, was defeated in the Senate Committee after having been overwhelmingly passed in the House. We believe that the bill was the victim of misinformation and an aggressive lobbying campaign by the opposition led by the AARP. The Committee will be evaluating this issue to determine future action.

Summary

The 1986 session saw the Association's lobbying effort reach a new high level of effectiveness, especially in the fight and final victory with SB 830. More members were directly involved in the process and the contributions of Mr. Judson Garrett proved to be invaluable. In the future the Committee will be establishing a more formal telephone contact system for emergencies. We will be reporting the results of the Fall elections and surveying the members for legislative contacts. Now, more than ever, it is important for members to contribute to the Pharmacy Political Action Committee and to the MPhA Lobbying Fund so we can maintain the level of activity necessary to protect the profession of Pharmacy in Maryland. Contact the MPhA office to find out how you can get involved.

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 5

Advising Consumers on OTC Vaginal Contraceptives

by **Thomas A. Gossel, R.Ph., Ph.D.**
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Ada, OH

and

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Cincinnati, OH

Goals

The goals of this lesson are to:

1. explain the mechanism of action and utility of commonly used spermicidal agents;
2. present the conclusions of an FDA advisory panel on OTC spermicidal products;
3. describe the reported relationship between the Today contraceptive sponge and carcinogenesis, and toxic shock syndrome;
4. discuss consumer advice about spermicidal products.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Objectives

At the conclusion of this lesson, the participant will be able to:

1. categorize each of the ingredients in OTC spermicidal products as to their safety and efficacy;
2. list the various types of vaginal contraceptive products and list their advantages and disadvantages;
3. compare OTC spermicidal contraceptives for efficacy with other methods of birth control;
4. summarize directions for correctly using the contraceptive sponge.

The human race is reported to be increasing by the rate of nearly 150 persons per minute, or 77 million persons per year. If this rate continues, by the year 2040 the world population will be 8 billion people, almost double the current 4.6 billion figure.

Regardless of whether an American woman is concerned about the total world population or her own family size, she desires control over her body and when she chooses to be pregnant. Therefore, OTC vaginal contraceptives are an integral component of family health care. Their availability to any person at any time is extremely important.

Consumers may choose from a variety of OTC or physician-prescribed contraceptives (Table 1). Each has advantages and disadvantages. Spermicidal agents applied within the vagina are the topic of this month's lesson.

TABLE 1

Comparative Effectiveness of Various Contraceptive Methods*

Method	**Pregnancies Per 100 Woman - Years**
Oral contraceptives	< 1 - 3
Intrauterine devices	< 1 - 6
Diaphragm with cream or gel	2 - 20
Vaginal sponge	2 - 20
Aerosol foams	2 - 29
Condoms	3 - 36
Spermicidal cream or gel	4 - 36
Rhythm - calendar method	< 1 - 47
Rhythm - temperature method	1 - 20

*Modified from Kastrup, EK et. al. (Eds): *Facts and Comparisons*, St. Louis, MO, F&C Division of JB Lippincott Co., 1984.

History

The introduction of substances into the vagina is the oldest recorded means for contraception, first reported in the 19th century B.C. Early Egyptians mixed honey natron (sodium carbonate) and crocodile dung to form a vaginal contraceptive paste. Oil of cedar and frankincense mixed in olive oil were in vogue in the 4th century B.C. Peppermint oil in honey, cedar gum, alum, and pieces of sea sponge were reportedly inserted into the vagina in the first and second centuries A.D. for contraceptive purposes.

In the 18th century, Casanova recommended squeezing a lemon and inserting it over the cervical opening. This cup-shaped lemon rind provided a physical barrier to sperm movement into the cervix. The citric acid also conferred spermicidal action.

The first commercial vaginal product was a suppository containing quinine sulfate in cocoa butter. This was manufactured in London in 1855. By the turn of the century, it was available in many countries. This was followed in the 1920's and 1930's with suppositories and foaming tablets containing ingredients such as mercury, quinine, lactic acid, boric acid, or burnt alum. With the discovery that several surfactants were effective spermicides, their use was popularized in the 1950's.

The use of vaginal contraceptives declined during the 1960's and early 1970's when oral contraceptive steroids made their debut. Later, intrauterine devices (IUD's) became popular. For awhile it seemed that this national trend away from OTC creams and jellies, and toward effective but potentially dangerous devices requiring physician supervision would continue.

Now, however, there is growing concern over the safety of oral contraceptives and IUD's, which are contraindicated for many women. Women are looking for alternate, safe means for birth control. Therefore, a resurgence of interest in OTC vaginal contraceptives has occurred. Except for sterilization, many people believe that OTC spermicides are the safest and most effective contraceptives.

Vaginal Contaceptives

OTC contraceptives (spermicides) are agents intended to be placed within the vagina. They consist of jellies, creams, foams, suppositories, foaming tablets, and sponges impregnated with spermicides.

These items provide contraceptive action in two ways. First, they physically prevent sperm movement through the cervical opening into the uterus and fallopian tubes. Secondly, they provide direct spermicidal or sperm-immobilizing activity before sperm can move into the upper genital tract.

An ideal spermicide meets the criteria outlined in Table 2. Currently available OTC products come close to meeting these requirements.

TABLE 2

Properties of an Ideal Spermicide

- Act rapidly and effectively; either kill *all* sperm on contact, or render them incapable of fertilization
- Systemically nontoxic, and nonirritating to the vaginal wall and penile membrane; be free of adverse long-term toxicity
- No effect on development of embryo or fetus, or development of nursing infant
- Inexpensive and readily available
- Aesthetic and easy to use
- Suitable for multiple uses per application

The FDA Advisory Panel on OTC Contraceptives and Other Vaginal Drug Products has reviewed all available data on spermicidal products. The results of this review and a categorization of spermicidal ingredients are summarized in Table 3.

TABLE 3

OTC Spermicidal Ingredients

Ingredient	Category
Dodecaethyleneglycol monolaurate	III*
Laureth l0s	III*
Menfegol	I
Methoxypolyoxyethyleneglycol 550 laurate and nonoxynol 9	III*
Nonoxynol 9	I
Octoxynol 9	I
Phenylmercuric acetate and phenylmercuric nitrate	II**
Other ingredients containing mercury	II**

*Safe; effectiveness remains unestablished
**Unsafe for OTC use

Surfactants

Surfactants (a contraction of the term "surface active agent") have been used as contraceptives since the 1950's. Unlike many of the earlier compounds, surfactants were effective and they did not irritate the vaginal lining or penile membrane. Many surfactant substances, including cationic, anionic, and nonionic chemicals, have been tested over the years. The nonionic substances have surfaced as the most effective contraceptives.

Nonionic surfactants (i.e., those which do not dissociate into positively or negatively charged ions) act directly on the lipid membrane of sperm. Their surface tension lowering capacity enhances their activity. This alters the sperm's membrane permeability characteristics and causes osmotic imbalance. In turn, the sperm's ability to absorb fructose, required for their metabolism, is reduced. This leads to a loss of motility and death of the sperm.

The two ingredients in current use in this country, **nonoxynol 9** and **octoxynol 9** are alkylphenyl polyoxyethylene nonionic surfactants. Octoxynol has a slightly different chemical structure than nonoxynol. However, both ingredients are equally safe and effective.

Menfegol, an agent used in foaming tablets elsewhere in the world, has been categorized as safe and effective by the OTC advisory panel. However, it has not been marketed in the U.S. at the time of publication of this lesson.

Effectiveness

Various studies have shown that between 1 and 30 percent of spermicidal users will become pregnant during a year of use. However, this should not be construed as an index of ineffectiveness of the products. The major reason for failure is improper use of the contraceptive rather than the particular spermicide product.

Many factors influence a product's effectiveness. These include proper placement, time required for melting to release the drug, and the duration of effectiveness. But the most important factor is compliance, i.e., the user following the directions correctly.

It is reported that foams are best. They are followed by foaming suppositories, creams, and jellies, in that order. Suppositories are convenient and easy to use, but may take 10 to 15 minutes to melt. One study showed that Encare suppositories were still intact 15 minutes after insertion in 9 of 20 women.

Safety

Surfactants have a long history of safe use. They have no known effects on the human embryo and no long-term adverse effects on the woman.

Recently, the potential for causing adverse effects to the user and the fetus have been questioned. It is known that these agents can be absorbed into the blood.

Several mechanisms for possible spermicide-induced congenital damage have been proposed. Some investigators believe that spermicides could injure sperm resulting in defective fertilization. This doesn't seem likely since the drugs work by destroying sperm cell membranes and rendering the sperm incapable of reacting with an ovum. Other researchers feel spermicides could damage the ovum before conception. If the spermicide were used after conception and it was absorbed, the embryo could be damaged on transfer from the mother through the placenta.

In one report based on 763 liveborn infants of mothers who had used a vaginal spermicide within 10 months of conception, the rate of congenital birth defects was 2.2 percent compared to 1.0 percent in a group of 3,900 women who did not use a spermicide product. Furthermore, it was reported that spontaneous abortion occurred nearly twice as often in pregnant women who had used vaginal spermicides compared to women who did not.

While there was a positive correlation reported, many still believe that the data were inconclusive. They state that the women reported to have used the spermicide were *presumed* to have used it during a period prior to conception. They further argue that the study was retrospective in design and time of exposure to the substance, and that proper use of the spermicide could not be accurately assessed.

Other more recent studies have shown that spermicide use is not associated with a higher birth defect rate or spontaneous abortion risk. The current rate of all serious birth defects diagnosed at the time of birth in the U.S. is 2 to 3 percent. To date, there have been few well-controlled clinical studies to prove or disprove a direct relationship. At this point in time, there does not appear to be a definite correlation between spermicidal use and biochemical/physiological changes in humans.

Category II (Unsafe) Ingredients

Phenylmercuric acetate was the only mercury-containing ingredient submitted to the OTC advisory panel for review. Phenylmercuric acetate *per se* is associated with a low incidence of systemic toxicity following absorption from the vaginal mucosa. Nevertheless, the panel cited information on mercury salts in general.

It is well known that mercury salts are absorbed vaginally and distributed systemically. This could be injurious to both the mother and developing fetus. It also enters the milk.

Both the human fetus and neonate are especially vulnerable to mercury toxicity. The damage is primarily associated with neurological and renal toxicity. In cases of contraceptive failure involving the use of mercury-containing vaginal contraceptives, overt symptoms of toxicity have not been noted to date in infants. There have been no specific systemic studies to assess potential long-term neurotoxicity or intellectual deficiency.

However, the panel determined that all mercury-containing ingredients could be expected to induce similar toxic reactions. Thus, it placed all mercury-based vaginal contraceptives in Category II (i.e., banned from future sale).

Contraceptive Sponge

Even though sponges have been used as contaceptives for centuries, the Today contraceptive sponge is the first one approved by FDA. It is a disposable, hydrophilic polyurethane mushroom-shaped device that contains one gram of nonoxynol 9. The device reportedly works in the following three ways.

1. It releases spermicide.
2. It blocks the cervical opening to penetration by sperm.
3. It absorbs seminal fluid.

The sponge possesses several distinct advantages over other OTC vaginal contraceptives. But it must be inserted properly to be effective. Most users experience no difficulty. However, because of its softness and shape, a few users report that it is more difficult to insert, remove, or check for proper fit than a diaphragm. If the removal strap is turned the wrong way, for example, it is quite difficult to remove.

Effectiveness

The product is still too new to establish long-term effectiveness data. Studies to date report a 10 to 27 percent pregnancy rate for users of the sponge compared with 8 to 12 percent failure with the diaphragm.

The sponge can be inserted up to 24 hours prior to intercourse. It provides continuous protection for a number of acts of intercourse. It is not necessary to leave the sponge in place for a 24-hour period, but it must not be removed before 6 hours after the last intercourse.

Adverse Effects

A few users have reported localized irritation, itching and rash with the use of the contraceptive sponge. However, less that 2 percent discontinue use because of these reactions. Occasionally the sponge will absorb vaginal lubricating fluids making intercourse painful. Rarely, it may be dislodged from the vagina.

Leaving the sponge in place longer than necessary can cause offensive odors from vaginal discharge or seminal fluid. Also, extended contact of the sponge with vaginal membranes may be a major factor in the development of toxic shock syndrome which has recently been associated with the product.

Toxic shock syndrome (TSS) is the result of a bacterial infection from *Staphylococcus aureus*. This microbe is one of many normally present in the vagina which constitutes part of its normal microflora. When the vaginal epithelium is irritated (as a result from numerous stimuli), the microbial balance may shift allowing increased colonization of pathogens.

When foreign objects (e.g., contraceptive sponges, tampons) are inserted into the vagina, there is an increasing chance for irritation to the vaginal epithelium. If *S. aureus* colonizes there, TSS may develop. Symptoms result from a toxin that is secreted by the colonizing bacteria and absorbed across the vaginal wall into the blood.

The development of TSS is minimized if the sponge is used correctly. In most of the women who have reportedly developed TSS after using the sponge, it has been shown that they did not follow directions properly. For example, one used the sponge too soon after childbirth. Others left the device in place longer than the recommended time (up to 5 days). One person inserted the sponge improperly, and while attempting to withdraw it, tore it into pieces. These pieces probably remained past the recommended period and irritated the vaginal mucosa.

The sponge itself does not cause TSS, nor does it predispose women to greater risk than would be expected from a tampon placed in the vagina. However, any woman who develops symptoms of TSS while using the sponge should contact a physician immediately. The symptoms include:

1. rapidly developing high fever (usually 102°F or more);
2. vomiting or diarrhea;
3. sudden drop in blood pressure (noted by dizziness);
4. generalized rash.

Odors may occur any time a foreign material is placed in the vagina and interacts with or collects vaginal fluids or semen. However, an odor that is stronger than normal or has a distinctly different smell may indicate the presence of infection.

Two or possibly three carcinogens are reported to be present in the sponge in trace concentrations. These are normal by-products associated with manufacturing techniques of both nonoxynol 9 and the sponge material. However, the concentrations of each of these are well below toxic levels. Furthermore, nonoxynol 9 has been used for decades without reports of cancer occurring.

One gram of nonoxynol 9 appears to be safe. Tests have shown that only about 200 mg of spermicide is released during a 24-hour period of use. Most spermicidal cream or gel products contain between 75 and 140 mg. per application.

Patient Advice

Since vaginal contraceptives are available without prescription, they are often used without medical guidance. The effectiveness of the product is directly related to the accuracy with which it is used. Compliance is the most important factor in successful product use.

Spermicides reportedly have certain advantages over other contraceptive products. They are safe and cause no serious local reactions or proven systemic effects. They are simple to use and ideal for persons who have intercourse infrequently.

On the other hand, they must be inserted at least 5 to 15 minutes, but no longer than one hour, before intercourse. Some individuals feel this removes the spontaneity from intercourse. The optimum time for insertion depends on the particular product and dosage form. Except for the sponge, a new application is necessary before each intercourse.

Applicators for foam products must be inserted deep into the vagina before releasing the product. Deposited too shallow, the product may drain out. Or, it may be too far away from where sperm will be deposited to be effective. Some foam products use a 5 ml applicator while others use a 10 ml applicator. This should not confuse the user. The smaller device requires two applications of product per use.

Because products are formulated into different bases, each may cause various degrees of irritation or burning. If one product irritates, another one having either different or the same spermicidal ingredient may be selected. Table 4 lists representative OTC products.

TABLE 4

Representative OTC Contraceptives That Meet The FDA Advisory Panel's Criteria of Safety and Effectiveness

Product	Form	Nonoxynol	Octoxynol
Because	Foam	X	
Conceptol Birth Control	Cream	X	
Conceptol Disposable	Jelly	X	
Delfen	Foam	X	
Emko	Foam	X	
Encare	Suppository	X	
Gynol II	Jelly	X	
Intercept Inserts	Suppository	X	
Koromex	Cream		X
Koromex	Foam	X	
Koromex	Jelly		X
Koromex II-A	Jelly	X	
Ortho-Gynol	Jelly		X
Ramses	Jelly	X	
Ramses Extra	Condom	X	
Semicid	Suppository	X	
Shur-Seal Gel	Jelly	X	
Today	Sponge	X	

Some recent reports have suggested that nonoxynol 9 and octoxynol 9 are effective antibacterials and antivirals. Preliminary studies have confirmed that the agents can kill the organisms that cause gonorrhea, genital herpes, and trichomoniasis. Consumers who ask about this potential activity should be told that the reports are as yet unproven. And, they should be reminded that if the chance for exposure to one of these causative organisms is great, then the spermicidal agents alone should not be relied upon for protection.

There is no evidence to prove that douching is an effective contraceptive. If a spermicide is being used, douching should be delayed for at least 6 hours after coitus because this could flush out the active spermicidal ingredient.

What's Ahead?

Researchers are actively searching for longer-acting forms of spermicidal products. One substance in clinical trial is gossypol. This has long been used in China as an oral contraceptive for men. It appears to have intravaginal spermicidal action as well.

Another substance currently under investigation in animal trials works by immobilizing sperm. It is reported to be 25 to 50 times more potent than nonoxynol 9.

One quite interesting study recently highlighted a possible spermicidal action of propranolol, a beta-adrenergic blocker. In this South American trial, nearly 200 women inserted propranolol vaginal tablets each evening, except during menstruation, regardless of when coitus occurred. The failure rate for the medication was recorded as 3.9 per 100 woman-years. The study also reported that intravaginally applied propranolol was effective for up to 10 hours. The mechanism of possible contraceptive action remains unknown.

Research will no doubt continue to develop newer contraceptives that are perhaps more effective than those currently available. Meanwhile, OTC spermicidal products can be recommended with confidence. If they are used correctly, they are both safe and effective.

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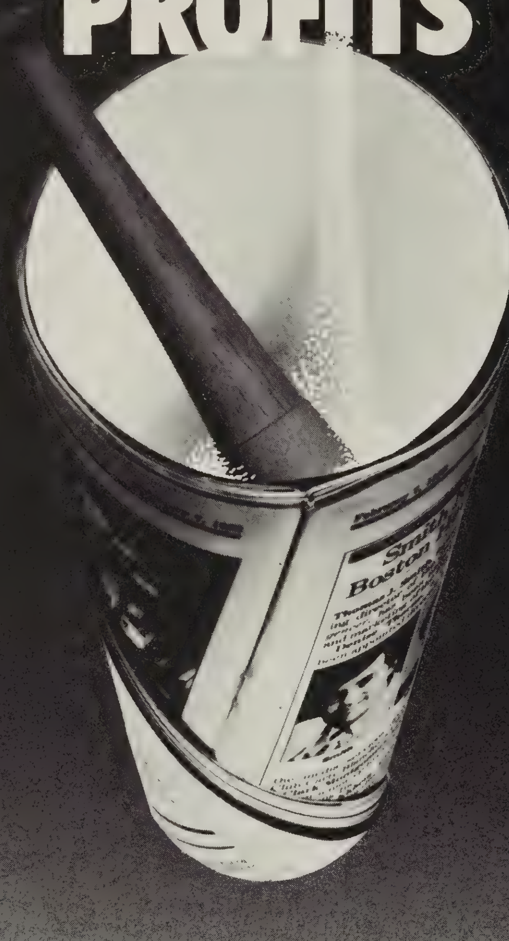

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IV. Elder-Ed Talk: Selecting the Right (Not Wrong) Over-The-Counter (Non-Prescription) Medication

by Madeline Feinberg and Peter P. Lamy

"Guaranteed to cure what ails ya"

OTC drug use is prevalent among the elderly. Not surprising! OTC's are easily obtained. Self-medication fosters a sense of independence. OTC's are "cheaper" than prescription medications. Many elderly grew up using home preparations. OTC's are widely advertised, particularly on television, where elderly get much of their information.

Most frequently, elderly complain of pain, arthritis, stomach problems, constipation, flu symptoms, all of which are indications for treatment with OTC drug products. Indeed, 30% of elderly's medication dollar may be spent on OTC's.

OTC drug use has a place in management of simple, self-limiting complaints, or reasonably short duration, even among the elderly. But elderly must recognize that providers—physician and pharmacist—must play a role in selection of the appropriate OTC, and that providers need to assist in monitoring the outcome of treatment. Elderly must recognize that OTC's can interact with prescription medications they may already be taking, and can interact with diseases they may have. Providers need to remember that elderly probably cannot read the package labeling, and may have difficulty understanding the information presented in all cases.

The subject of OTC drug use is the second most popular topic which we present to senior audiences and to health care provider groups. We have targeted the four major categories of OTC's most frequently used by elderly and we present major considerations for consumers and providers.

Remember, OTC's may not necessarily cure what ails ya!

I. INTRODUCTION
  1. Introduce yourself
  2. OTC's—medicines you can buy without a prescription
     —are they safe to use?
     —do they really work?
     —can they interact with prescription medicines?
  3. When to consider using an OTC
     —for minor ailments
     —for short periods of time

II. GUIDELINES FOR PRODUCT SELECTION
  1. First step: diagnosing the problem
     —experienced symptoms before?
     —minor or severe problem?
     —pain or other limiting factors?
     —asking friends or neighbors for advice
  2. Once the problem is diagnosed, do we need a medication?
     —e.g. The Common Cold: with medication it may last seven days, without medication, it may last a week!
  3. OTC's are
     —medicines that *do* work
     —medicines that *can* interact with other medicines
     —medicines that *can* make certain conditions you may have worse: (ask for examples) e.g. aspirin and peptic ulcer disease, antihistamine (sleeping medicine) and prostate problem
  4. Problems with some OTC medications:
     —alcohol content
     —sugar content
     —salt content
     —hidden ingredients
  5. Using the pharmacist to assist in product selection, you should
     —know what prescription medications you are taking
     —know what non-prescription medications you may be taking
     —know your medical history (problems with medications, allergies?)

PART I. GUIDELINES FOR OTC ANALGESIC USE: PAIN RELIEVERS

I. Making a diagnosis: what is causing the pain? Emphasize! Aches and pains are not a normal accompaniment of aging. Pain is due to injury or disease.

II. THREE MAJOR CHOICES: *ASPIRIN, ACETAMINOPHEN, IBUPROFEN*

Important! Elicit audience participation. Seniors are very knowledgable (but may also be misinformed). Get it out into the open with discussion.

- A. *Aspirin*
  1. List therapeutic uses
     - —relief of pain of headache, joint pain, toothache, etc.
     - —reduces fever
     - —reduces inflammation
     - —thins blood (inhibit platelet aggregation). How much?
     - —*prescribed* to prevent stroke or MI for certain at risk patients
  2. List common side effects
     - —stomach irritation (pain). Emphasize: take with food and plenty of water to reduce!
     - —bleeding (may be painless, Symptoms: black, tarry stool)
     - —rash or other allergic reaction (caution: use in asthma patients)
     - —sedation
  3. When you may have to *avoid* taking aspirin
     - —history of gout
     - —other medications (anticoagulant, oral hypoglycemic, other NSAIDs, other)
     - —history of ulcers
     - —bleeding disorders
     - —allergy
  4. Kinds of aspirin available: (elderly particularly misinformed as to types of products available)
     - —plain (brand name or generic—most important, Fresh!)
     - —buffered (explain reason for buffering)
     - —coated (explain use of coated products)
     - —liquid (watch sodium, effervescent products)
     - —mixed with other ingredients (antihistamine, caffeine)
     - —strengths (regular, extra, arthritis-strength)
  5. Hidden aspirin
     - —in OTC's—with cough and cold products, with antacids
     - —in RX products—Fiorinal®, Equagesic®, Soma Compound®, Robaxisal®
  6. Storage: avoid moisture and heat (medicine cabinet)
     - —describe stale aspirin (odor, crystal formation)
- B. *Acetaminophen*
  1. List therapeutic uses:
     - —relief of pain
     - —reduces fever
  2. List side effects associated with use
     - —none at normal doses (some controversy?)
  3. When to avoid:
     - —does not interact with most medications
  4. Kinds of acetaminophen available
     - —generic (significant cost savings)
     - —liquid dosage form available (watch sugar content)
     - —tablets, capsules, caplets (explain "no differences")
     - —strengths
     - —combined with other ingredients in RX and OTC
- C. *Ibuprofen*—Newest on market! Many know product as Motrin®
  Explain difference between RX and OTC is *strength* of product.
  1. List therapeutic uses—Be careful! Remember, we are talking about OTC indication ONLY, not RX.
     - —relief of minor aches and pains
     - —reduces fever
     - —primary dysmenorrhea (of interest to elderly?)
  2. List side effects: Most important: age may increase possibility of adverse reactions. Do not exceed dosage.
     - —stomach irritation: Very important, same precautions as with aspirin
     - —may interact with other conditions elderly may already have (cardiovascular, renal, CNS)
     - —hypersensitivity; cross-reaction with aspirin
  3. When to avoid:
     - —history of ulcer
     - —bleeding disorders
     - —kidney problems
     - —high blood pressure
     - —fluid retention
     - —other medications (Dilantin®, sulfonamides, sulfonylureas, anticoagulants, diuretics, medications for blood pressure, lithium)
  4. Products available: OTC currently Advil® and Nuprin®
     - —generic products may soon be available.

PART 2. COUGH AND COLD PRODUCTS

I. Making a diagnosis—the common cold
- —caused by a virus (no cure)
- —runny nose or stuffiness
- —sore throat
- —cough (dry or productive)
- —fever (slight)

—aches and pains

II. What you can do without taking medications:
 - —rest
 - —fluid (hydration important: mention chicken soup)
 - —eating well
 - —vaporizer
 - —gargle

 If your cold is serious and requires medical attention
 - —fever over 101°F
 - —pain (moderate to severe)
 - —can't breathe or catch breath
 - —mucus which is thick, greenish or bloody
 - —rash
 - —symptoms which last more than one week

III. Choosing a product to provide relief of symptoms:
 No product provides complete relief
 Avoid combination products (more costly and may not need all ingredients for your symptoms)
 1. What to take for aches and pains:
 aspirin or acetaminophen
 2. What to take for sore throat:
    - —gargle
    - —hot tea
    - —hard candy
    - —lozenges (benzocaine—avoid if allergy: watch sugar content)
 3. What to take for runny nose and congestion:
    a. Decongestants (topical: nasal spray: systemic: tablets or syrups)
    But avoid if:
       - —you take medication for high blood pressure (it causes heart palpitations)
       - —thyroid problems
       - —diabetes

    May cause:
       - —overstimulation
       - —paradoxical drowsiness
       - —dependence, if using nasal preparation. Follow directions.

    Do not use nasal sprays (or drops) and oral decongestants at the same time

    b. Antihistamines (tablets or liquids)
    Avoid if:
       - —prostate problems
       - —certain types of glaucoma

    May cause:
       - —drowsiness
       - —may interfere with vision
       - —interact with prescription medicine you are taking
 4. What to take for cough:
    - —expectorant, brings up mucus, need to drink plenty of fluids for it to work properly
    - —dextromethorphan ("D.M.") cough suppressant for dry, hacking cough
    - —codeine, a narcotic, requires a prescription in Maryland.

PART 3. LAXATIVES

I. Making the diagnosis: What is constipation?
 "Change in normal bowel habits."
 - —discuss "mythology" of daily bowel movements

II. What you can do to prevent constipation
 - —activity
 - —fluids
 - —bulk in diet
 - —setting aside special time of day, do not postpone urge

III. Choosing the Right Product
 1. To *prevent* constipation
    a. bulk laxatives—first choice to prevent (if constipation is due to poor bulk intake)
       - —explain mechanism of action
       - —how to take correctly—plenty of fluids
       - —takes 12 hrs–3 days to work
       - —types of products: may be some differences
       - —watch out for sugar and salt content
       - —may be mixed with other laxative ingredients
       - —take by itself. Do not mix with other medications!

    b. stool softeners—for dry, hard stools (may be caused by drug therapy)
       - —surfactant action
       - —take with plenty of fluids
       - —may be recommended for long term use, non irritating, not absorbed, non-caloric
       - —does not interact with other medications
       - —recommend generic since there is considerable differences in price
 2. To *cure* constipation—occasional use only!
 List some dangers of frequent laxative use = "abuse"
    - —atonic colon ("lazy gut")
    - —nutrient depletion
    - —electrolyte imbalance
    - —dehydration
    - —interference with absorption of medications

    a. stimulant laxatives—Do not exceed recommended dose
       - —explain mechanism of action (8 hours to work)
       anthraquinones (e.g. cascara, senna)
       diphenylmethane (bisacodyl, phenolphthalein)
       - —take with plenty of fluids
       - —may cause cramping
       - —potential allergic reaction

    b. saline laxatives—MOM
       - —explain mechanism of action
       - —need for adequate fluid intake
       - —may absorb ingredients (magnesium) with serious toxicity upon long-term use
       - —after evacuation, recommend one glass of water to replace fluids lost

c. lubricant laxatives—mineral oil
  - —mechanism of action
  - —no longer recommended, but elderly may prefer
  - —emulsified products (more palatable)
  - —toxicity of mineral oil use over long term
  - —impair absorption of fat-soluble nutrients
  - —do not give to frail elderly—risk of aspiration pneumonia

d. Castor Oil
  - —used for rapid evacuation of digestive tract
  - —mechanism of action: works in small intestine, hence prolonged use may promote dehydration, nutrient depletion and electrolyte imbalance
  - —should not be used for constipation, but for special procedures requiring cleansing of bowels.

e. Suppositories: glycerin, bisacodyl
   Enemas:
  - —may cause rectal irritation
  - —care must be taken to properly administer
  - —should not be used routinely

3. Need to watch for
  - —sugar content in oral products
  - —salt content
  - —excessive use!

PART 4 ANTACIDS

I. Making the diagnosis: "Hyperacidity"
  - —ulcer
  - —indigestion
  - —"Heartburn"
  - —sour stomach

  Distinguish from pain in substernal region. Could be heart attack! The correct diagnosis may save your life!

II. Types of products available:
  - —liquids (best for immediate relief)
  - —chewable tablets (convenience, may be uncomfortable to denture wearers)
  - —chewing gum preparations, chewy tablets
  - —with anti-gas ingredients (simethicone)
  - —products containing aluminum are constipating
  - —products containing magnesium cause diarrhea
  - —products have different potencies (explain that sometimes a teaspoonful will be sufficient, while with other products 1–2 tablespoons may be required). Be sure to understand directions for use! Neutralizing capacity.
  - —taste may be a factor (suggest chilling)
  - —generic products widely available which are equivalent to more popular brands

  1. Special precautions
    - —mixing with other medications
    - —if pain does not go away—seek medical help quickly
    - —do not use more than two weeks, may be symptoms of more serious conditions
    - —be certain when is correct time to take medication
    - —watch out for sugar and salt content
    - —avoid sodium-containing preparations (bicarbonate of soda)

In summary, most important . . . making the right choice is not easy when given all the possible choices. Ask the pharmacist for assistance. The price you pay for your medication includes the professional fee for the pharmacist assistance. Use it!

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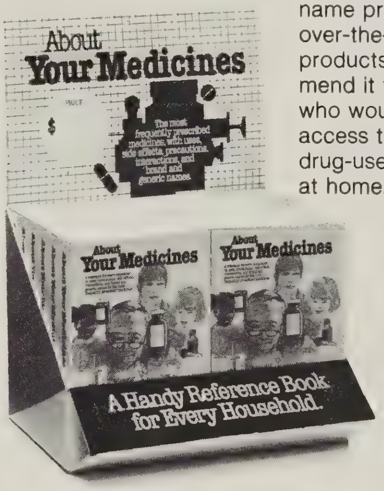
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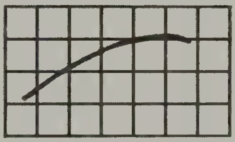
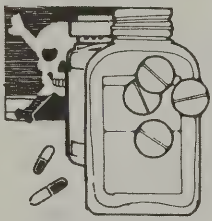


National spending for health care registered its lowest increase in 20 years in 1984—rising 9.1% above the 1983 amount, the U.S. Department of Health and Human Services has announced. Hospital services, by far the largest single item—accounting for $158 billion of the total health care tab of $387 billion, grew only 6.1%, accounting for much of the slowdown in spending. HHS Secretary Margaret Heckler credited "reduced emphasis on inpatient care coupled with greater reliance on outpatient treatment" for the good news. Though drugs are obviously playing a more important role than ever before, drugs and sundries accounted for just 6.7% of the health care dollar in 1984—the same as the year before. Spending for these products totaled nearly $26 billion, 9.4% above the 1983 figure. Though the rate of increase for drugs was slightly more than the overall rate, the biggest jumps were turned in for dental services (15%) and physicians (10.2%).

Childhood Poisonings



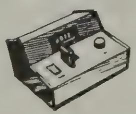
A study by the U.S. government's Consumer Product Safety Commission has found that a third of all children under five who had swallowed drugs accidentally had taken their grandparents' medicines. The study will be expanded nationwide to see if similar results are obtained. While parents appear to be doing an increasingly better job of keeping medicines out of the hands of their children, grandparents often leave drugs on bedside tables and other areas accessible to their grandchildren. The 1985 poster commemorating National Poison Prevention Week called attention to this growing trend with the theme, "Protect Your Children & Grandchildren from Poisoning." Pharmacists should remind their elderly patients that all medicines should be securely stored away whenever children are visiting.

Conglomerates on Rise

Health Plan

Some health care experts are predicting that within a decade health care will be in the hands of 10 to 15 giant conglomerates. Under this theory, all the nation's physicians, pharmacists, nurses, and other health professionals would be working for these large enterprises. Such thinking has been fueled by the recent announcement that a group of 450 major nonprofit hospitals has agreed to offer health insurance under a new conglomerate. The new venture—the Voluntary Health Plans of America—comes on the heels of the expansion by large, profit-making hospitals into health insurance, and marks the latest move in the consolidation of health care. "The whole health care industry is changing," an official of the new venture commented. "We're not just hospitals—we're health care systems." Hospitals in the new organization represent 12% of the total hospital beds in the country and 20% of the total hospital revenue.

Home Diagnostic Kits



A newly released study from Decision Research Corporation has found that 60% of consumers are willing to use home diagnostic kits currently available in pharmacies. Asked if they would use kits "that allow people to test for medical conditions themselves at home, like pregnancy, blood pressure, and other things, before or instead of going to a doctor," 35% of the consumers said they "somewhat" agreed and 25% said they "strongly" agreed. Sales of home diagnostic tests were estimated to reach $84 million last year, and are projected to grow at an annual rate of more than 30%—rising to about $250 million by 1988.

Provided as a service by the American Pharmaceutical Association.

Patient Aid

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Or may keep me wide awake.
Some will help my cool to keep,
Or let my depression break.

Whatever may ail me,
My pills will not fail me,
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What the Doc may prescribe,
I shall gladly imbibe
To seek my good health from a bottle

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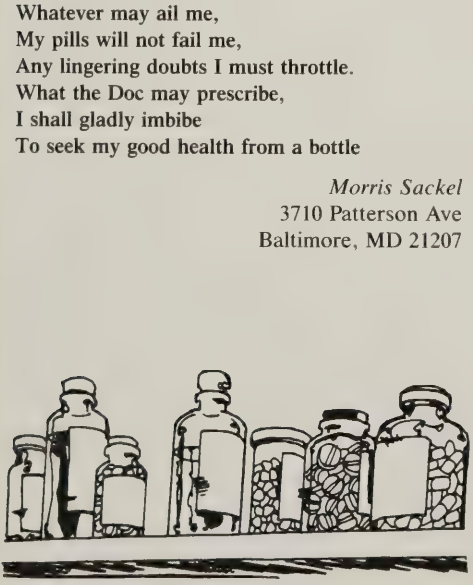
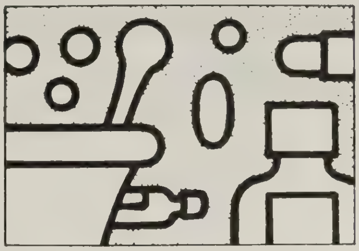


Things You Should Know FOR YOUR GOOD HEALTH



Keep Cool in Summer Months

In periods of extended hot weather such as we are experiencing now, we are in danger of being victims of the heat. There are basically three types of heat-related conditions.

Heat cramps are relatively simple and easily controlled. This condition develops in some individuals who are subjected to prolonged exposure to high temperature and who drink large amounts of water because of excessive sweating, hence losing a great deal of body salt. Indications of heat cramps are severe muscle cramps and pain (especially in the calf of a leg and the abdomen); faintness and dizziness; exhaustion.

The treatment of heat cramps consists of increasing salt intake. In mild cases, salt taken in 5-10 grain coated tablets will allay the symptoms; more severe cases may require medical attention to promptly relieve the condition by giving salt solutions intraveneously.

Heat exhaustion is another condition in which high temperature is a contributing cause. (A careful distinction must be made between heat exhaustion and heat stroke, since different treatments are necessary for each of these conditions.)

Heat exhaustion is the less serious of these two conditions. In its early stages it is characterized by fatigue and faintness followed by profuse clammy perspiration, whiteness of the skin (redness in heatstroke) and brief loss of consciousness — cold, clammy skin, weak pulse and shallow breathing.

The treatment for heat exhaustion is:

1. Remove the victim to as cool and comfortable a place as possible, place in reclining position, and loosen or remove clothing. Place cool moist cloths on forehead and wrists.
2. If no response, hold aromatic spirits of ammonia near the nose, as a stimulant.
3. If these measures are not immediately effective, raise legs above victim's body and bandage each leg rather tightly from the ankles toward the body, in order to force the blood from the legs back into circulation.
4. Give the victim salt tablets or a salt solution (salt dissolved in water) by mouth if conscious, otherwise by means of a retentive enema.

Upon recovery, do not allow the victim to sit up for some time; keep him quiet and in a cool place until entirely recovered.

Heatstroke (or sunstroke) is a far more serious condition than heat exhaustion. Heatstroke is connected with a cessation of sweating or inability to dissipate the heat generated by muscular exertion, which leads to the rise in body temperature. The victim collapses and the skin will be flushed, very dry and very hot with slow breathing. Treatment must begin immediately:

1. Call for medical attention.
2. Place the victim in a tub of very cold water.
3. When the body temperature has been lowered to about 100°F, remove the victim to a bed, wrap him in wet, cold sheets.
4. Check his temperature every few minutes.

Recovery from heatstroke is very slow, and careful medical supervision is essential.

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"Timely Topics"

The Parke-Davis Center for the Education of the Elderly, University of Maryland School of Pharmacy, is sponsoring this monthly column addressing "what's new" on issues of disease management in the elderly. At the conclusion of each topic in the series, a sample Elder-Ed talk on the subject covered will be outlined and can be added to the repertoire of community programs which are most frequently requested by older audiences. The first topic being covered is osteoporosis.

Although calcium supplementation is not the only factor to consider in prevention of osteoporosis, it has become the buzz word for osteoporosis. Public awareness is high, yet there is a great deal of confusion about products, required amounts, price factors, and the actual role of calcium in the prevention and progression of this disease. Part III deals solely with the calcium issues.

For copies of previous columns, contact the Maryland Pharmaceutical Association

Madeline Feinberg, Pharm BS
Director, Elder Health Program
University of Maryland School of Pharmacy

Timely Topics—Osteoporosis
Part III. The Calcium Strategy

Introduction

A causal relationship between calcium deficiency and osteoporosis is supported by the following observations:

- calcium deficiency in experimental animals causes osteoporosis,
- elderly Americans have low calcium intake,
- calcium supplementation reduces bone loss.[1]

Most researchers now recommend daily elemental calcium intake of 1,000 mg for adults and 1,500 mg for postmenopausal women, yet the average daily intake for American adults may be less than 500 mg. Hence supplementation is recommended throughout adulthood to maintain a positive calcium balance.

It is necessary to evaluate each person's dietary intake before recommending a supplement, since the goal of supplementation is to assure that total intake meets the recommended amounts. This will vary among individuals. Following this article a brief guide to calcium content of common food sources is given.

Certain patient related factors must also be taken into consideration when supplementation is recommended. Patients with a history of renal stones, increased calcium absorption, or other hypercalcemic conditions should take calcium only under the supervision of a physician. Dietary factors and patient behaviors, such as reduced gastric acidity, high protein intake, high phosphorus intake or high alcohol consumption may reduce ability to absorb calcium.

Calcium supplements are widely available and are now being added to breakfast cereals and snacks, in addition to the large number of branded and generic products. The opportunities for patient and provider confusion is great. The following article will discuss in detail factors which need to taken into consideration by pharmacists who purchase these products and make recommendations to patients. At the conclusion, some common misconceptions of consumers will be highlighted with suggested pharmacist response to these issues.

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[1] Anon: Osteoporosis—consensus conference. J Am Med Assoc 252:799–802, 1984.

Factors Affecting Dissolution and Absorption of Calcium Supplements

by Ralph F. Shangraw, Ph.D.
Professor and Chairman
Department of Pharmaceutics
University of Maryland
School of Pharmacy
Baltimore, Maryland 21201

There is much confusion in the literature on the subject of calcium absorption and the factors which affect it. For many years, it was thought that all calcium supplements were equivalent as long as equivalent amounts of calcium ion were being administered. There is considerable doubt today that this premise was correct.

It is well known that in order for drugs to be absorbed they must first go through a dissolution process. However, little attention has been paid to the role of dissolution in calcium supplements. An excellent review of the bioavailability of calcium was written by Allen in 1982 in which the various factors affecting calcium absorption were discussed (1). This article notes that calcium must be in a soluble and probably ionizable form before it can be absorbed and that the presence of gastric acid appears to increase the solubility of calcium complexes or salts. Upon reviewing the various dietary factors which negatively affect calcium absorption (such as phytates, oxalates, phosphates, fiber) all have an effect of reducing calcium solubility. Milk or milk products on the other hand seem to increase absorption which could be due to the presence of soluble calcium lactate or increased acidity or delayed transit time through the gastrointestinal tract.

However, the choice of calcium supplementation has for the most part ignored the solubility of the calcium salts in vivo. As a matter of fact many studies on calcium absorption pay little or no attention to the form in which the calcium is administered. Greater emphasis has been placed on calcium load (the relative amount of calcium present in each salt) and whether or not the calcium comes from a natural source such as ground up oyster shells or is chemically precipitated.

As can be seen in Table I, the calcium load varies widely depending up on the salt form. Both calcium carbonate and calcium phosphate have been widely used as sources of calcium because they contain higher percentages of calcium per gram of salt and thus smaller quantities have to be administered. This is a very important consideration because the recommended dose of calcium is 1000 mg. For instance in order to ingest 1000 mg of calcium, it would be necessary to ingest almost 10 grams of calcium gluconate, but only 2.5 grams of calcium carbonate. Again, this is assuming that all of the calcium is soluble under physiological conditions which is certainly not always the case.

Table I
Relative Calcium Loads of Various Salts

Salt	% Calcium	Grams of salt containing 100% RDA (1000 mg. Ca^{++})
Calcium Carbonate	40	2.5
Calcium Sulfate	36.1	2.8
Dibasic Calcium Phosphate	29.5	3.4
Tribasic Calcium Phosphate	38.8	2.6
Calcium Lactate	18.4	5.4
Calcium Gluconate	9.3	10.75
Calcium Ascorbate	10.3	9.75
Calcium Citrate	24.1	4.15

Calcium Carbonate

The most widely used calcium salt for supplementation is calcium carbonate. Calcium carbonate is available as ground up oyster shells or may be precipitated chemically. There is no data that one form is superior to the other as a supplement. The naturally occurring products such as oyster shell do have small traces of other metal contaminants, but there is no evidence that these are present at anything approaching unsafe levels.

Calcium carbonate is practically insoluble in water but does react with hydrochloride acid (in the stomach) to form calcium chloride which is highly soluble and available for absorption. However, as the solution continues down the tract and pH increases, it is reconverted to insoluble calcium salts, mainly the carbonate. If for some reason the tablet never disintegrates and/or the pH of the gastrointestinal tract is never highly acidic (achlorhydria) then it is possible that calcium is never solubilized and therefore never available for absorption.

While studying the effect of pH on the disintegration and dissolution of commercial calcium carbonate supplements, it was found that a number of commercial products disintegrate or dissolve very slowly in .1NHCl acid (which mimics the pH of the stomach). Using standard tests described in the United States Pharmacopeia, most name brand products, Os-Cal®, Caltrate®, Supplical®, Tum®, met disintegration and dissolution standards, but many private label and generic products did not. In most cases, this appears to be due to the failure of the products to disintegrate. Because nutritional supplements do not have to meet standard tests, it appears that many have been poorly formulated. It is obvious that many private label companies have not exhibited the necessary concern for bioavailability. Unfortunately, this is often not a consideration with nutritional supplements. Some companies have apparently over compressed their tablets and others have removed starch (a principle disintegrating agent) in order to promote their products as starch free. At the present time, a number of private label companies are reformulating their calcium carbonate tablets but until these products are in channels of distribution, it is advised that pharmacists receive assurance from their suppliers about the disintegration or dissolution characteristics of private label products. There are often considerable cost savings in non-brand products, but these cost savings are worthless if the product is substandard.

Effect of pH on Dissolution of Calcium Salts

One of the major factors complicating the bioavailability of calcium salts is the influence of pH in the dissolution process While the solubility of some salts (mostly those with low calcium loads such as lactate, citrate, gluconate) are relatively pH independent, this is not true for the solubility of calcium carbonate and is of even greater concern in the case of calcium phosphate and calcium sulfate, all of which are pH dependent.

Calcium supplementation is widely used in postmenopausal women, a group which has a relatively high rate of impaired stomach acid production. In such a group of patients, absorption of calcium might be expected to be depressed, due to the lack of solubility of some calcium salts at pH's found in achlorhydria.

The solubility of calcium carbonate, but particularly calcium phosphates (dibasic calcium phosphate, tribasic calcium phosphate) are depressed as the pH of the gastrointestinal tract increases. In a recent study, Recker compared the absorption of calcium in its carbonate form with a pH adjusted citrate form in achlorhydric and normal subjects (2). Fractional calcium absorption from the two forms exhibited no difference in normal subjects, but under fasting conditions, the absorption of carbonate was substantially lower in achlorhydric patients. The solubility of tribasic calcium phosphate is even poorer than the carbonate at elevated pH's. For instance at a pH of 4.78 only 10% of calcium triphosphate (Posture®, Ayerst Labs) dissolved in 900 ml of dissolution fluid using standard USP procedures compared to 78% for calcium carbonate (Os-Cal®, Marion Labs). That means that a patient taking 600 mg of calcium in the form of tricalcium phosphate with 3 oz (90 ml) of water would dissove less than 6 mg of calcium.

Calcium Content of Common Food Sources

Food source	Elemental calcium
Skim milk (one cup)	300 mg
Low fat yogurt (one cup)	400 mg
Ice cream (half cup)	100 mg
Swiss cheese (one ounce)	250 mg
Cottage cheese (one cup)	215 mg
Cheddar cheese (one ounce)	200 mg
Raw broccoli (1" × 5")	100 mg
Canned salmon (one cup with bones)	
One orange	

Taking calcium carbonate or phosphate in the evening on a resting stomach is also probably ill-advised. Acid secretions are minimal and most stomach contents are quickly cleared into the duodenum where pH rises quickly. On the other hand, calcium lactate solubility is independent of pH and time of administration is not critical.

Obviously it is necessary to take factors other than solubility into consideration in choosing a calcium supplement. Some persons with lactose intolerance may have difficulty in taking large numbers of calcium lactate tablets. As the number of tablets a patient has to take increases, compliance decreases. In some cases it may be necessary to go to a chewable tablet or liquid product when patients have problems in swallowing.

Following is a list of summary statements:

1. Calcium carbonate is one of the least expensive forms of calcium available and requires the ingestion of smaller quantities of tablets to obtain equivalent amounts of calcium.
2. The quality of some commercial calcium carbonate products particularly those sold under private label is questionable. In order to counsel patients, pharmacists should demand disintegration and dissolution data from suppliers of all calcium supplements before stocking those products in their pharmacies. While disintegration does not assure dissolution, lack of disintegration clearly indicates a poor product.
3. Calcium carbonate tablets should not be taken on a fasting stomach or at night when acid secretion is minimal. This is particularly true in achlorhydric patients. Taking tablets with meals with maximize acid secretions and solubility.
4. There is no doubt some achlorhydric patients will not benefit from calcium carbonate supplements because the pH of their gastronintestinal tracts is

never high enough to assure solubility.

5. The dissolution of calcium phosphates and particularly tricalcium phosphate is so poor at even slightly elevated gastrointestinal pH's that its usefulness in achlorhydric or even in normal patients is highly questionable. Any possible benefit from less gas evolvement (which is seen in some patients using calcium carbonate) is more than offset by calcium phosphate's poor dissolution patterns.
6. Persons who are known to suffer from achlorhydria should consider the use of soluble calcium salts such as the lactate or citrate even though compliance may be more of a problem due to the number of tablets needed.
7. The use of dolomite and bone meal have no advantages over calcium carbonate and may be less soluble and have been known to contain traces of lead.

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1. Allen, LH, Calcium bioavailability and absorption: a review, Am. J. Clinical Nutrition, 35, 783–807 (1982).
2. Recker, RR, Calcium absorption and achlorhydric, New Eng. J. Med., 313, 70–73 (1985).

Common Misconceptions Regarding Calcium Supplementation Among Consumers and Suggested Pharmacist Response

Misconception	Suggested response
1000 mg–1500 mg calcium is a megadose* and therefore dangerous *megadose is 10 times the RDA. Since RDA is 800 mg, it is insufficient, and the recommended amount does not meet definition of "megadose"	These amounts are normal daily requirements now recommended by most researchers.
Everybody needs to take 1,500 of calcium daily in the form of a supplement.	Daily needs depend on dietary intake. Hence amount recommended must be individualized.
Natural calcium such as dolomite or bonemeal is best.	Calcium can be natural or synthetic. Natural products however, may be contaminated with lead or arsenic. Of greater concern is the magnesium content, particularly when large doses are taken regularly.
Calcium cures high blood pressure.	Low calcium intake is often observed in individuals with high blood pressure, yet a causal relationship has not been proven and the number of patients in the studies has been small.
Antacids are a good source of calcium	Due to the popularity of Tums®, many consumers believe that all antacids are calcium supplements. People taking antacids may assume that their calcium needs are met, or may inadvertently purchase a product which does not contain calcium.

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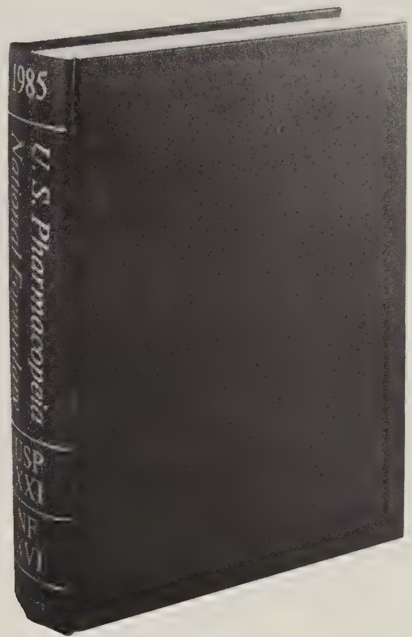

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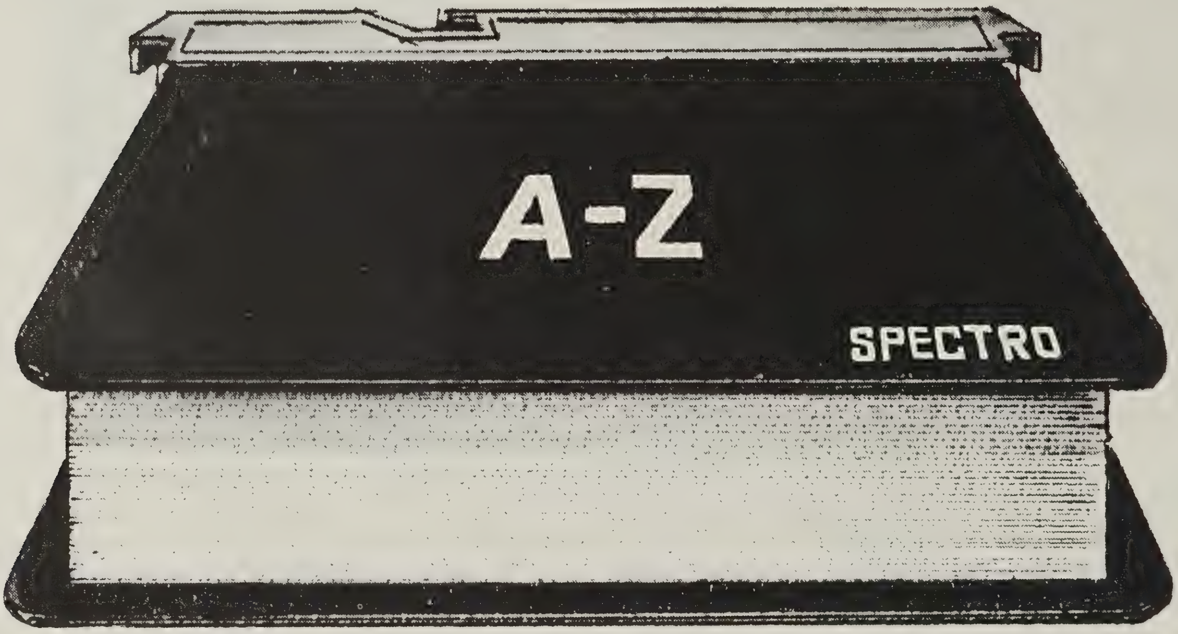

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Bumetanide

by Eric Schuetz

Bumetanide, (Bumex) by Roche is a sulfonamide diuretic for use in the management of edema associated with congestive heart failure, hepatic disease, and renal disease. Similar to furosemide, it acts on the ascending Loop of Henle to inhibit sodium and chloride absorption. Renal excretion of sodium, chloride, potassium, hydrogen, calcium, magnesium, ammonium (and sometimes phosphate and bicarbonate) are all increased, while uric acid excretion is decreased. Renal blood flow is increased due to dilation of renal vasculature. The hypotensive effect results from decreased plasma volume.

The usual oral dose of Bumetanide is from 0.5 to 2 mg daily in one dose or two divided doses. If the parenteral route is indicated, Bumetanide may be administered IV or IM at a dose of 0.5 to 1 mg given every two to three hours as needed until the desired response is reached or up to 10 mg/day. Bumetanide is currently available as 0.5 and 1 mg tablets, and as 0.25 mg/ml injection.

Possible adverse effects of Bumetanide use include muscle cramps, dizziness, hypotension, headache, nausea, and encephalopathy. Fluid and electrolyte depletion may result, especially with excessive doses, too frequent administration of the drug, or in patients with restricted sodium intake. Possible drug interactions with Bumetanide include diuretics, digoxin, lithium, hypotensives, indomethacin, probenecid, ototoxic drugs, nephrotoxic drugs, and anticoagulants.

Bumetanide has a half life of from one to one and a half hours and is highly protein bound (up to 96% protein bound.) It is rapidly and completely absorbed from the G.I. tract reaching peak plasma concentration in 0.5 to 2 hours. It is approximately 72% bioavailable. Given intramuscularly, peak plasma concentration occurs in 1–2 hours. Given intravenously, peak plasma concentration occurs in 15–30 minutes. As for elimination, Bumetanide is 50–60% renally cleared.

Another use of Bumetanide is for enhancing the elimination of drugs or toxic substances following intoxication, (for example, forced diuresis following aspirin overdose.) Other things to note about Bumetanide are its use in severe renal failure, where high doses may be needed, its use in patients allergic to sulfonamides, where extreme caution should be exercised, and the importance of educating patients on the signs and symptoms of electrolyte depletion.

Bumetanide—Patient Information

Bumetanide (pronounced BYU-MET-AN-IDE) is a diuretic—it causes your body to rid itself of excess fluid which may have accumulated because of heart failure, liver failure, or kidney failure. It may also be used to lower your blood pressure.

Before using this medication, tell your doctor:

—if you are allergic to or had an unusual reaction to Bumetanide, or to a sulfa drug,

—if you are pregnant, or intend to become pregnant while on this medication or if you are breast feeding an infant,

—if you have any of the following problems: diabetes, diarrhea, gout, kidney disease, or liver disease.

—if you are taking any other medicines—prescription or non-prescription.

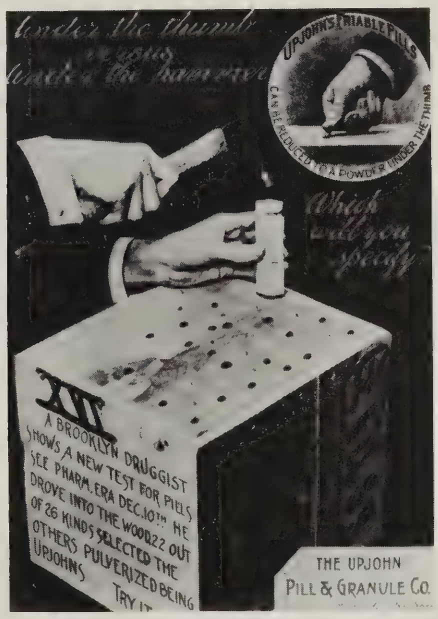
Taking Bumetanide may cause a feeling of tiredness, also an increase in urination. These effects should decrease after you have taken the medicine for a while. To prevent this from interrupting your sleep, you could take it first thing in the morning (if you are taking a single daily dose.) Or if you are taking more than one dose per day, take the last dose no later than 6:00 PM, unless otherwise directed by your physician. To put it simply, plan your doses in such a way that it will least likely affect your activities and sleep, and take them at the same time every day. If you miss a dose, take it as soon as possible—*unless* it is almost time for your next dose, in which case skip that dose, then go back to your regular dosing schedule. **Do Not Take A Double Dose.**

Some of the side effects that may be experienced from taking Bumetanide include dryness of the mouth, increased thirst, irregular heartbeats, mood or mental changes, muscle cramps or pain, nausea, vomiting, unusual tiredness or weakness, weak pulse, ringing in ears, and skin rash. Less common side effects include chest pain, dizziness, headache, premature ejaculation or difficulty in keeping an erection, and stomach cramps or pain.

There are several important things to remember while taking Bumetanide. Remember to have your doctor check your progress at regular intervals. Your doctor may want to prevent the loss of potassium or replace potassium lost from your body by having you either eat or drink foods high in potassium such as citrus fruits and bananas, by having you take a potassium supplement, or by having you take another medicine to prevent the loss of potassium. Do not change your diet on your own—consult your physician first. Also notify your doctor if you become sick, especially with continuing vomiting or diarrhea. And before having surgery, even dental work, make sure the doctor knows that you are taking Bumetanide.

Eric completes this article as part of a special studies rotation in the association office. He is a graduating Pharmacy Student from the University of Maryland School of Pharmacy

The Board of Directors of the National Pharmaceutical Council has elected Douglas J. MacMaster, Jr. Chairman for 1986. MacMaster is President of the Merck Sharp and Dohme Company.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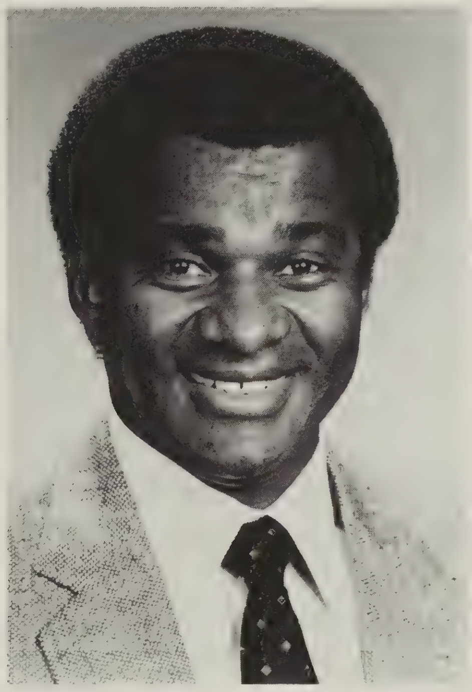

Theodore Connelly has been named district manager of the mid-Atlantic hospital district by Syntex Laboratories. He resides in Columbia, Maryland.

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LETTERS

Dear Dave:

In response to many inquiries, the following is a series of questions and answers concerning Upjohn's development of the use of minoxidil as a topical solution for hair growth. This information also responds to often-asked questions from physicians and pharmacists about the use of LONITEN® Tablets (minoxidil) in extemporaneous topical formulations. The main purpose in disseminating this information is to provide an increased level of understanding and awareness of Upjohn's position regarding the current prescribing and dispensing of minoxidil in compounded topical solutions.

Question 1: What is the status of Upjohn's program to develop REGAINE® Topical Solution as a topical minoxidil product?

In 1977, The Upjohn Company began a formal project to explore the possibilities for using minoxidil topically to grow hair. In 1983, Upjohn began a study involving more than 2,300 volunteers in 28 locations around the United States. This multicenter study, completed in 1985, was designed to assess the efficacy of REGAINE Topical Solution in the treatment of male pattern baldness. Its completion marked the end of Upjohn's first phase of the clinical development of topical minoxidil.

After completion of the analysis of the data from this study and a thorough evaluation of the safety and efficacy of topical minoxidil under the conditions of the study, Upjohn filed a New Drug Application (NDA) with the Food and Drug Administration (FDA) on December 19, 1985.

Additional clinical studies of REGAINE Topical Solution are currently in progress, studying the effects of this drug for a number of indications in addition to male pattern baldness. Upjohn expects to be in a position to comment on these studies at some future date.

Question 2: What are Upjohn's general concerns over extemporaneously formulated topical minoxidil preparations?

Over the past few years many news reports concerning the REGAINE development program have appeared. Some of these reports have been extremely optimistic concerning the clinical potential for REGAINE Topical Solution. In spite of this enthusiasm, Upjohn has consistently cautioned interested parties that the topical use of minoxidil has not yet been approved by the FDA as being safe and effective for hair growth.

The NDA for REGAINE Topical Solution, like all NDAs, is required to contain information on manufacturing practices and quality control procedures. Strict adherence to FDA-approved manufacturing and control procedures will be required of Upjohn when and if REGAINE Topical Solution is approved for marketing by the FDA. Quality control, with its attendant implications for both safety and effectiveness, cannot be taken for granted. Upjohn's experience in the clinical evaluation of REGAINE Topical Solution clearly indicates the need for consistent formulation of the drug in compliance with Good Manufacturing Practices as set forth in regulations of the FDA. Equally important, the drug must be accompanied by adequate instructions for use.

Reports appearing in the media have suggested that non-Upjohn sources of topical minoxidil solutions available from time to time over the past several years have varied widely in composition. Many of these non-Upjohn sources of topical minoxidil are apparently derived from reformulation of Upjohn's LONITEN Tablets. Patients using topical minoxidil under such conditions have no assurance of attaining effects comparable to those experienced under the conditions of the Upjohn clinical trials of REGAINE Topical Solution.

Upjohn has been and continues to be concerned that the availability of non-Upjohn sources of topical minoxidil solutions will adversely affect the introduction of REGAINE Topical Solution when and if approved by the FDA. As a result, Upjohn has been and is taking steps to discourage extemporaneous topical formulation and use of minoxidil. One recent step has been the revision of the package insert for LONITEN Tablets.

Question 3: What does the package insert for LONITEN Tablets indicate concerning the use of minoxidil for hair growth?

Upjohn's package insert for LONITEN Tablets contains an express and unambiguous warning against use of the product for hair growth.

The package insert for LONITEN Tablets, under the PRECAUTIONS section, item 10, provides the following:

> Use of LONITEN Tablets, in any formulation, to promote hair growth is not an approved indication. Clinical trials are in progress and are designed to determine efficacy, dosage, duration of treatment, and actual side effects. Pending completion and analysis of these trials, efficacy, dose and duration of the therapy are not known. Because systemic absorption of topically applied drug may occur and is dependent on vehicle and/or method of use, extemporaneous topical formulations made from LONITEN should be considered to share in the full range of CONTRAINDICATIONS/WARNINGS/PRECAUTIONS/AND ADVERSE REACTIONS listed in this insert. In addition, skin intolerance to drug and/or vehicle may occur.

Question 4: What is the current patent position of Upjohn regarding REGAINE Topical Solution?

A patent was issued to Upjohn in 1979 (United

States Patent No. 4,139,619) claiming the topical formulations of minoxidil, including the drug REGAINE Topical Solution itself. The claims in the patent also cover the method of using minoxidil for hair growth. A second patent with related claims is expected to be issued within the next several months. Both patents will expire in 1996.

Question 5: How does the Upjohn patent position relate to the traditional freedom of physicians in prescribing drugs?

Upjohn is aware of the traditional prerogative of physicians to select and make available appropriate treatment for their patients without outside interference with the patient-physician relationship. Historically, Upjohn has not used its patent rights to interfere with this relationship by preventing an individual physician from privately treating a patient with a therapy patented but not marketed by Upjohn. Nonetheless, the use of the advertising media to promote the availability of patent-infringing topical minoxidil products is now being undertaken by many individuals in a manner that directly challenges Upjohn's patent position. Because of the substantial investment Upjohn has made in the development of REGAINE Topical Solution, the curtailment of patent infringing activity through the assertion of Upjohn's patent rights has become a high priority for Upjohn.

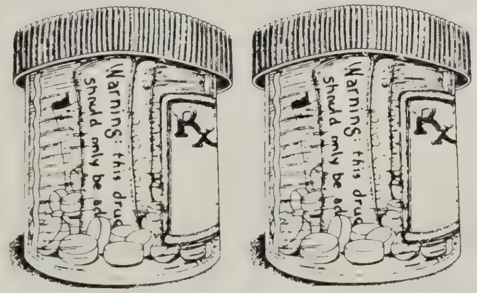
The patent infringement activities mentioned above may also adversely affect the introduction of REGAINE Topical Solution when and if approved by the FDA.

Question 6: What does Upjohn currently regard as an "infringement" of its patent rights?

While in many cases they do unknowingly, physicians who prescribe, pharmacists who formulate, and patients who use topical minoxidil formulations are infringing and/or inducing the infringement of Upjohn patent rights. Infringement takes place even if minoxidil is purchased from Upjohn in the form of LONITEN Tablets. Purchase of LONITEN Tablets carries with it no license, either express or implied, under any patents of Upjohn.

I trust that you and your associates will find this information useful.

Sincerely,
Jack M. Newcomb
The Upjohn Company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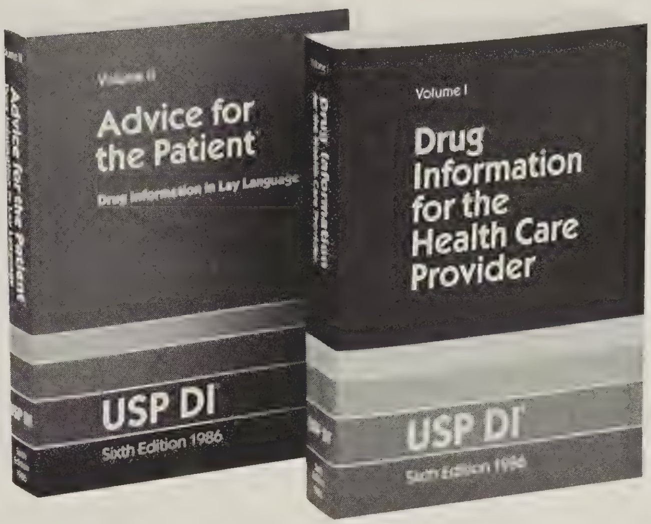

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Dickinson's Pharmacy

by Jim Dickinson

Mail-order: a disaster waiteth. "It's big business, and getting bigger," my lunch companion from industry said. "They're doing over $20 million a year."

Nothing could stop it, he said. We were talking about mail-order prescriptions, and the way some of the big drug chains are getting into it. To help everything along, mail-order prescriptions are being offered as an attractive option to cost-beseiged employers by third-party programs such as PAID Prescriptions, recently acquired by Porex Technologies Corporation, owner of the vast Medco (National Pharmacies) mail-order house.

In addition, the 17 million-member American Association of Retired Persons/National Retired Teachers Association mail order prescription drug operation in Washington, D.C. has long been the biggest single prescription processing center in the country.

The over-65s age group is the fastest-growing age group in the country, and by the year 2025, more people will be middle-aged to elderly than will be young.

All of which adds up to a cosmic chain-reaction atomic boom in mail order prescriptions, right? You betcha—I'm buying all the stock I can get my hands on.

And why not—poor old Grandma, who can't afford $100-per-pill biotech miracle arthritis cure-alls that we're now inventing because zero-deficit Gramm-Rudman federal spending levels won't raise her Social Security or extend Medicare to ambulatory Rxs, has to get her low-cost medications without walking to the drug store—which means the mail-order option. Right?

Even if she could suffer the pain in her joints enough to stagger out to the HMO or chain drug store two bus sections away from her high rise, she'd probably get mugged by unemployables on the way—which is further grist to mail-order Rx mill. Right?

Lots of people who think they're close to where it's at see this as a clearcut scenario for our future, just a few years from now.

That's really the bottom line as to why legislative action against mail-order prescriptions is so hard to get started. In addition, there are other obvious reasons—for-profit independent pharmacists charge more per Rx than mail order houses do, and everything they say on this subject is biassed in their own economic interest, so it can be disregarded.

Also, we don't have a body-count we can lay on the mail-order houses' doorsteps.

Not yet, we don't. But as a society, we're working on it. It'll soon be here.

Nobody wants to see it, and those anti-mail-order protagonists out there would all wish they could win their point without a body-count, but the political/public opinion battlefield will demand solid proof before it sanctions this particular form of restraint-of-trade.

So look for bodies. They'll come in the following ways:

(1) As mail order programs begin competing with each other, the mail order option will get into the color supplements of the Sunday papers. Ours is better, faster than theirs—our patient profiles protect you against interactions whereas they don't have any. After a while, traffickers and junkies will figure out that the mailboxes in the old-folks' apartments across the way have drugs in them.

(2) Mail carriers will get robbed, drawing more publicity to this problem. Controversy will start on whether "certain" mailmen on particularly hazardous routes should carry guns, go in pairs, or be accompanied by attack dogs.

(3) The wrong people will accidentally get mail-delivered prescriptions—e.g., a visiting grandchild, mental incompetents, etc.—and there will be more reported deaths from this cause than at present (there are some, now).

(4) Drugs will get contaminated by Postal Service mechanized handling and occasional mishaps (broken containers, loosened closures, become subject to unusual temperature/moisture/smoke/volatile gases in environments sometimes encountered by the mails).

But until any of these things actually happen, and there is an actual body-count to bring before Congress and/or the state legislatures, all this is simply defamatory theory, uttered only for selfish reasons by those who stand to gain economically if mail-order prescriptions and all their many public benefits are in any way restricted. Understand?

This feature is presented on a grant from Mylan Pharmaceuticals, in the interests of promoting the open discussion of professional issues in pharmacy. Mylan Pharmaceuticals accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of Mylan Pharmaceuticals.

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We have recently been informed of the sudden passings of Robert Rejoinis, U. of M. class of 1971, Benjamin Ginsberg, class of 1931 and Jerome Shermack. We deeply regret the loss to family, friends and the profession of Pharmacy.

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Advising Consumers on OTC Menstrual Products

— Thomas A. Gossel
— J. Richard Wuest

Spinning on Stools Allowed

— Dolly Merrit

Two Views of Grass Roots 21

— Evelyn Farinas
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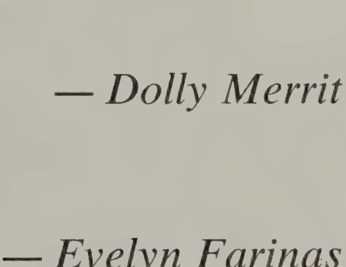
Insurance Checklist for Small Business

— Mark R. Greene

Timely Topics: Osteoporosis — An Elder Ed Talk



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President's Message

I have thoroughly enjoyed serving as your President during the 1985–86 year and communicating with you through this column. But since this is the last President's Message that I am responsible for, I thought I would give the "Last Word" to the individual who served as Honorary President during my year, Dr. Peter Lamy.

Madeline Feinberg,
PRESIDENT

MY LAST WORD

By
Peter P. Lamy, PhD

Pharmacy, we were told some time ago, is an Information System. Pharmacy's strength rests in its ability to organize, evaluate, and give information, a process that has become much more important with the burgeoning home health care market, where lack of supervision of long-term care drugs and monitoring of their effects is one of the major reasons for adverse drug reactions in the elderly.

How well, though, can we perform this increasingly necessary function? What kind of support do we have?

Nomifensin was removed from the market with very little information given to pharmacists. BW marketed a new antidepressant and, while the first ads began appearing in the medical journals, it had already been withdrawn from the market, because the therapeutic dose was too close to the dose that could, and did, induce seizures in some patients. McNeil's long-awaited nonsteroidal analgesic was finally marketed, but pharmacists had to read in the newspapers that there were unanticipated side effects, i.e. unexplained severe flank pain in a small number of patients, indicative of a reduction in kidney function status. There was a "Dear Doctor" letter, but no "Dear Pharmacist" letter. We simply cannot function as an "Information System" if we are third or fourth in line as recipients of information.

Perhaps the School's proposal of a computer-driven Bulletin Board will help. Right now we could use it to highlight information in many areas. Is calcium really effective in hypertension and in prevention of colorectal cancer? Is fiber use, suggested by the National Cancer Institute, really a factor in prevention of cancer? Or can it induce calcium deficiency when too much is used (it apparently can). What kind of fiber? From California comes research that tells us that soluble fiber (for example psyllium hydrocolloid) can, indeed, be responsible for increased cell proliferation—and, therefore, cancer. What do we tell our numeorus customers who take this preparation?

Scientists and nutritionists could not agree on a revision of the RDAs, something that has never happened before. Yet, there is renewed concern about the use of megadoses of vitamins, and the possibility that even some water-soluble vitamins, administered in megadoses, can be the cause of clinically important toxicities. As pharmacists, we dispense a lot of vitamins. How do we counsel our patients?

Unsolved, still, is our reaction to the NIH Consensus Report on multiple analgesic use. Do we counsel elderly, who so often take a non-steroidal with acetaminophen, that this could, over the years, lead to a heightened risk to kidney problems?

Clearly, we need to address new ways to receive, evaluate, and given information much better than we have been able to do in the past. Where is that Bulletin Board?

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 6

Advising Consumers on OTC Menstrual Products

by Thomas A. Gossel, R.Ph.,Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, OH

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to:

1. discuss the cause and treatment of primary dysmenorrhea and distinguish it from premenstrual syndrome;
2. present the recommendations of the FDA/OTC advisory panel that reviewed OTC menstrual product ingredients.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Objectives

At the conclusion of this lesson, the successful participant should be able to:

1. define dysmenorrhea and premenstrual syndrome, and differentiate between primary and secondary dysmenorrhea;
2. list four pharmacologic classes of drugs used to treat primary dysmenorrhea;
3. classify various ingredients of OTC menstrual products into appropriate FDA categories;
4. state specific patient advice to relate to consumers purchasing an OTC menstrual product.

Sometimes described as "the woman's curse," or "the cramps," dysmenorrhea is the most common cause of gynecological symptoms. It affects more than half of all fertile American women and is not well understood by health practitioners and consumers. Therapy is, therefore, largely empirical.

Throughout the years, a wide assortment of home remedies and proprietary products have been used to ease the symptoms of dysmenorrhea. Whereas the majority of these treatments have been based on subjective responses and anecdotal observation rather than objective reasoning, others have at least been based on theoretical value.

Recently, an FDA OTC advisory panel of medical experts reviewed over 70 active ingredients of OTC products purported to be beneficial in alleviating menstrual disorders. The recommendations of this advisory panel are summarized in this month's lesson. Additionally, current concepts advanced to explain a possible etiology of dysmenorrhea are examined. Dysmenorrhea is also differentiated from a separate, but frequently confused condition, premenstrual syndrome.

Background

"Dysmenorrhea" is derived from the Greek word that means painful or difficult menstrual flow. In fertile women, it is the major cause of loss of days from school and work. About 10 percent of affected women miss an average of 1 to 3 days each month.

There are two forms of dysmenorrhea. **Primary (spastic, intrinsic) dysmenorrhea** refers to the syndrome that exists in the absence of pelvic pathology. It is the more common type, accounting for approximately 80 percent of all cases of menstrual pain.

Secondary (extrinsic, acquired) dysmenorrhea results as a consequence of an underlying organic disorder such as benign uterine tumors, endometriosis (inflammation of the uterine mucosa), or cancer. The presence of an intrauterine device (IUD) may cause secondary dysmenorrheal discomfort. The condition can be suspected whenever menstrual discomfort first appears after age 20. The pain of secondary dysmenorrhea normally begins several days before onset of menstruation. The pain is more constant than that with the primary form and continues throughout menstruation, perhaps even to several days following cessation of flow.

The basic cause of secondary dysmenorrhea must be treated by a physician. Symptoms of the primary form are generally self-treatable. Therefore, OTC products are indicated for persons with primary dysmenorrhea.

The **premenstrual syndrome (PMS)** is occasionally and erroneously referred to as a third type of dysmenorrhea. Premenstrual syndrome and dysmenorrhea are separate conditions having different etiologies, although some symptoms overlap. The cause of premenstrual syndrome may be a progesterone deficiency or estrogen excess. Alternatively, recent research suggests that it may be due to improper activation of the renin-angiotensin-aldosterone system.

Premenstrual syndrome is also called congestive dysmenorrhea, premenstrual tension, or the premenstrual tension syndrome. Tension is only one symptom of the syndrome, however, so this terminology is not always descriptive of the actual condition.

Premenstrual syndrome is a recurring symptom complex that starts 2 to 12 days before onset of menstruation. It reaches a peak shortly before menses, and normally ceases once the flow begins. However, some women may continue to experience symptoms throughout their cycles. Symptoms consist of those listed in Table 1.

TABLE 1

Symptoms of Premenstrual Syndrome
Depression, crying
Irritability, anxiety
Tension, insomnia
Lethargy, fatigue
Mood swings
Dizziness
Dull pelvic ache
Backache
Headache
Headache, migraine
Muscle and joint pain
Peripheral edema
Bloated feeling in abdomen
Tender breasts
Weight gain
Bowel irregularities
Skin changes (urticaria, pruritus, acne)

Dysmenorrhea, on the other hand, is characterized by symptoms that begin a day or two before menstruation, continue through menses, and clear at the end. It occurs only during ovulatory cycles. Women may experience 1 to 2 menstrual cycles per year without dysmenorrhea. These occur during months when ovulation does not occur.

Primary dysmenorrhea generally appears first within 6 to 12 months after menarch (the time at which a female begins to menstruate). Symptoms are noted 1 to 12 hours prior to commencement of menstruation. Occasionally they begin with the onset of menstrual flow or slightly after. Pain is maximal the first 2 to 24 hours, then tapers off over the next 1 to 2 days.

Symptoms worsen with age, peaking in the late teens or early 20's. Dysmenorrhea occurs more commonly in overweight or in sedentary women. It is also more frequent in women who have regular, rather than irregular menstrual periods. Dysmenorrhea is less severe in women with frequent sexual intercourse, and occasionally improves after childbirth.

Pain is described as a constant low abdominal aching. Additionally, there may be a sharper pain described as "colic-like," that is cyclic in nature. Cycles recur every few minutes to hours and persist 30 to 60 seconds. Pain may radiate to the lower back, vagina, or the inner thighs. Associated responses may include nausea, vomiting, diarrhea and fatigue. Occasionally, the sufferer will report nervousness, irritability, dizziness, and faintness. Some women experience increased menstrual flow during the painful spasms. Not all symptoms of primary dysmenorrhea or premenstrual syndrome may be observed in every patient. However, the symptom pattern is fairly consistent in most individuals.

Causes of Dysmenorrhea

Menstruation. Early civilizations did not understand the process of menstruation. Frightened by the unknown, menstruating women were sometimes shunned and even punished. During the years of the Roman Empire, Pliny the Elder, in his treatise, *Natural History*, commented on menstruation as, ". . .nothing could easily be found that is more remarkable than the monthly flux of women; contact with it turns new wine sour, crops touched by it become barren, grass dies, seeds in gardens are dried up, and the fruit of trees fall off." Even in more recent times, natives of the MaeEnga tribe of New Guinea believed that blood from a menstruating woman, or even contact with a menstruating woman, was harmful to a man and might even cause his death.

Hippocrates in the fifth century B.C. believed that dysmenorrhea was caused by cervical obstruction. This blocked the menstrual discharge, causing it to stagnate and induce discomfort. Today it is known that cervical obstruction may indeed cause retention of menstrual discharge with resultant irritation and contractility of uterine muscle. The pain characteristics in persons with known cervical obstruction differ from those of dysmenorrhea, however. So it is unlikely that the "obstructive theory" is a plausible explanation.

It is generally believed that symptoms of dysmenorrhea and premenstrual syndrome are caused by an imbalance of normal prostaglandin levels. Those prostaglandins believed to be involved are synthesized in the endometrium, the mucous lining of the uterus. Levels of both prostaglandin $F_{2\mathrm{alpha}}$ and prostaglandin E are known to be increased.

Prostaglandin $F_{2\mathrm{alpha}}$ stimulates the myometrium (muscular wall of the uterus). This in turn causes pain due to ischemia (inadequate oxygen supply). Ischemia develops because the muscular contraction requires an increased blood flow, and blood cannot be delivered quickly enough. So, pain develops much like chest pain in susceptible persons with angina pectoris. This theory is logical since dysmenorrhea often decreases after childbirth; and during gestation, there is increased vascularization with increased blood supply to the uterus.

In women with dysmenorrhea, the uterine muscle is also believed to be more sensitive than normal to prostaglandin $F_{2\mathrm{alpha}}$. Furthermore, prostaglandins may also cause a release of bradykinin and histamine which are potent vasodilators. They, in turn, irritate nerve endings and cause further pain. Other symptoms (nausea, diarrhea, etc.) may be induced by circulating prostaglandins. The initial event that causes prostaglandin release to precipitate symptoms remains unknown. It could be neuronal, hormonal, or even psychological. It is known, for example, that oral estrogen-progesterone therapy, or sympathomimetics can control dysmenorrhea. Psychological conditioning also helps in certain individuals.

The prostaglandin-induced theory is now generally accepted as the basis for understanding dysmenorrhea and developing new drugs to treat it.

On the other hand, not all women with primary dysmenorrhea have elevated prostaglandin levels. Furthermore, not all women respond to prostaglandin synthesis inhibitors. Therefore, there still may be other, yet undiscovered causes.

Treatment

Through the years, remedies have consisted of inhaling vapors of various herbs, applying heat, and taking opium, nitroglycerin and alcohol. Surgical removal of the ovaries was performed in severe cases.

More recently, drugs to treat symptoms of premenstrual syndrome and primary dysmenorrhea have been restricted to several pharmacological classes. These include analgesics, diuretics, smooth muscle relaxants, and antihistamines. The FDA Advisory Review Panel on OTC Miscellaneous Internal Drug Products evaluated ingredients on empirically related clusters of symptoms. It considered pain (muscle stiffness, headache, cramps, backache, fatigue, and general aches and pains), water-retention (weight gain, skin disorders, painful breasts, swelling), and negative affect (crying, loneliness, anxiety, restlessness, irritability, mood swings, depression, tension) to be most appropriate for evaluating effectiveness of the agents.

The panel has reported its findings on ingredients included in OTC menstrual products. It classed these ingredients as Category I (generally recognized as safe and effective), Category II (unsafe and/or ineffective), or Category III (safe, but effectiveness not yet substantiated). These recommendations are summarized as follows.

Analgesics

Pain of primary dysmenorrhea and premenstrual syndrome is classed as mild to moderate in intensity. The analgesics listed in Table 2 were shown by the FDA/OTC panel to be safe and effective for treating this type of pain.

Aspirin. Since the pain of dysmenorrhea is presumably caused by prostaglandins, aspirin probably works, at least in part, by interfering with prostaglandin synthesis. The other salicylate derivatives most likely act in a similar manner.

TABLE 2

Category I Ingredients For OTC Menstrual Products

- Salicylates (aspirin, calcium carbaspirin, choline salicylate, magnesium salicylate, sodium salicylate)
- Acetaminophen
- Ibuprofen*
- Ammonium chloride
- Caffeine (as diuretic)
- Pamabrom
- Pyrilamine maleate

*Determined by the FDA Arthritis Advisory Committee rather than the OTC advisory review system.

Acetaminophen. Acetaminophen is equivalent to aspirin on a mg-to-mg basis for noninflammatory pain. This includes pain associated with primary dysmenorrhea and premenstrual syndrome.

Ibuprofen. Ibuprofen was unanimously recommended by the FDA Arthritis Advisory Committee to be switched from prescription-only status to OTC availability. Its switch to OTC status involved a different system than previous status changes through the FDA/OTC advisory panel efficacy review. It was the first FDA-initiated conversion of a major drug. One of its OTC indications is the treatment of primary dysmenorrhea.

Many studies that compare ibuprofen with aspirin and/or acetaminophen rate ibuprofen significantly better on a mg-to-mg basis. In treating pain of primary dysmenorrhea, 200 mg of ibuprofen is equivalent to or greater than 650 mg of aspirin or acetaminophen. Moreover, there does not appear to be any difference in the character of pain relief when ibuprofen is given after onset of pain compared to administration before it occurs.

Codeine. Codeine, taken in doses of 30 to 60 mg, is safe when used under physician supervision. However, because of its potential for causing physical dependence, the advisory panel concurred it is not safe for OTC use as an analgesic. It, therefore, placed codeine in Category II. A different OTC advisory panel indicated that safe doses lacked conclusive proof of effectiveness of codeine as a single ingredient analgesic and rated it as Category III.

Caffeine. Used alone in doses of 100 to 200 mg every 3 to 4 hours, caffeine is safe for self-administration, but ineffective as an OTC analgesic. Substantial evidence supports caffeine use at a dose of 65 mg (up to 600 mg per 24 hours) with analgesics, yielding enhanced pain relief activity. Therefore, the advisory panel placed caffeine in Category III, indicating that manufacturers can conduct appropriate clinical trials to assess its role in menstrual pain relief. If these studies are successful, caffeine can remain on the market in combination with analgesic agents indicated for alleviating dysmenorrhea

Diuretics

The only proper use for an OTC diuretic is to help eliminate fluid that accumulates during the premenstrual and menstrual periods. Symptoms of water-weight gain, bloating, swelling, and/or full feeling should be relieved. Each of these symptoms is self-diagnosable, self-limiting, and not associated with a potentially serious underlying disorder. The panel members, therefore, indicated that these symptoms could be self-treated.

The exact cause of fluid accumulation during the premenstrual period is not known. Fluid is not always present. But it is generally accepted that this edema, which occurs in various organs, is responsible for many of the symptoms of dysmenorrhea.

Ammonium Chloride. Ammonium chloride is the most commonly used of the so-called "acidifying diuretics." Doses up to 3 grams per day are safe for OTC use. Individuals with renal and/or hepatic disease should avoid the drug. In persons with impaired kidney function, progressive hyperchloremic acidosis can result. In persons with liver disease, symptoms similar to hepatic coma have been reported.

Ammonium chloride is absorbed from the gastrointestinal tract and the ammonium ion is converted in the liver to urea. This frees the chloride, which reacts with sodium bicarbonate to form sodium chloride. This then causes increased sodium chloride elimination which takes water with it. The diuretic action is limited to 3 to 4 days because, by then, the kidney begins to produce ammonia. This ammonia combines with hydrogen to form ammonium ion that will be excreted along with chloride ion from above, negating the overall diuretic effect.

Thus, ammonium chloride has limited application for long-term use. It is suitable for inducing a short-term fluid loss.

Caffeine. Though classed as a questionable analgesic, caffeine is a safe and effective diuretic in doses of 100 to 200 mg every 3 to 4 hours. Caffeine increases the glomerular filtration rate in the kidney. This action enhances water output, although sodium, calcium, potassium and chloride ions, and to a lesser extent, urea, are also excreted. The FDA advisory panel concluded that caffeine could be recommended to relieve symptoms of water-weight gain, bloating, swelling, and/or full feeling associated with the premenstrual and menstrual periods.

Caffeine was classed by still another OTC advisory panel as a Category I central nervous system stimulant at doses of 100 to 200 mg every 3 to 4 hours. Thus, it is also effective for symptoms of fatigue associated with the premenstrual period.

Pamabrom. Like caffeine, pamabrom is also a xanthine derivative. A dose of 50 mg up to 4 times per day is safe and effective for self-administration. In one study, doses of 800 to 1600 mg pamabrom were given for 5 to 7 days to pregnant women with edema. There were no symptoms of toxicity. The overall pharmacological effects of pamabrom are similar to those expected with caffeine.

Theobromine Sodium Salicylate and Theophylline. Both of these share several pharmacologic actions with other xanthines. Both are also safe for OTC use. Neither ingredient, however, has yet been established as an effective diuretic. Thus, both substances will be allowed to remain on the market, at least temporarily, as long as studies to prove their efficacy are ongoing.

Smooth Muscle Relaxants

The panel did not place any smooth muscle relaxant ingredient in Category I. Homatropine methylbromide was classed as Category II. Homatropine, like other anticholinergics, is unsafe for self medication at doses required for pharmacological activity.

Cinnamedrine Hydrochloride. This agent was also placed in the "needs more study" category. It is safe at usual doses of 15 to 30 mg every 4 hours up to 120 mg per day, but there are insufficient data to establish its effectiveness. Cinnamedrine is an unsaturated tertiary amine similar in structure to ephedrine. Although some other drugs with similar structures are recognized as being smooth muscle relaxants, cinnamedrine must undergo the appropriate clinical studies to substantiate its effectiveness.

Antihistamines

Pyrilamine Maleate. This antihistamine was shown to be safe and effective in doses of 25 to 50 mg every 3 to 4 hours, or 60 mg every 12 hours (maximum 200 mg/24 hours) for OTC use in relieving symptoms of the negative affect and water-retention clusters, and pain of cramps and backache of the premenstrual and menstrual periods. Pyrilamine also has mild local anesthetic and analgesic activities. The advisory panel stated that pyrilamine was unique among antihistamines in that it possessed certain pain relief and diuretic properties. It has been traditionally marketed in combination with other ingredients in OTC products for relief of premenstrual tension.

Its mechanism of action is unknown and may be based partly on an antihistamine effect. It in known that the amount of histamine in the body increases and decreases with fluctuations in estrogen levels during the menstrual cycle. Or, the mechanism may be through reducing prolactin levels with a secondary reduction in synthesis of prostaglandins. There is some evidence that pyrilamine may also directly inhibit prostaglandin action on the uterine musculature.

The advisory panel concluded that pyrilamine maleate is generally recognized as effective in relieving premenstrual symptoms of the negative affect and water-retention clusters. It is also effective in relieving pain of cramps and backache in both the premenstrual and menstrual periods. If it is indicated for relief of any menstrual or premenstrual symptom, it must be marketed in combination with a diuretic or diuretic and analgesic.

Vitamins

Pyridoxine Hydrochloride (vitamin B_6). This vitamin has been cited in the literature as effective for symptoms of primary dysmenorrhea and premenstrual syndrome. Pyridoxine is safe in doses up to 200 mg. daily for OTC use. However, its effectiveness still needs to be demonstrated clinically.

Botanical Herbs

A wide variety of preparations, usually as the alcoholic extracts, containing botanical or vegetable herbs have been used in OTC products since the early 1800's. The panel reported that detailed studies have not been conducted to assess effectiveness of any of these ingredients, and certain ones are known to be toxic. The panel classed all herbal ingredients as Category II.

Combinations of Ingredients

As explained earlier, the premenstrual syndrome and primary dysmenorrhea are separate clinical entities. So it is logical to combine ingredients to treat the multiple symptoms concurrently. While some symptoms are common to both, others occur predominately in one or the other condition. For example, symptoms of water-retention are commonly seen in the premenstrual syndrome, but are less common in dysmenorrhea. Pain and cramping, on the other hand, are common to both conditions. It is, therefore, rational to combine an analgesic with a smooth muscle relaxant. However, since there are currently no proven safe and effective smooth muscle relaxants, combining a known Category I analgesic with an unproven smooth muscle relaxant would result in an ineffective combination product. Remember, the test for efficacy of a combination drug in this country is that *all* active ingredients must contribute to the total therapeutic effect. There are two combina-

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tions that meet this test: a diuretic with an antihistamine, and a diuretic, antihistamine, and analgesic. Such combinations may continue to be marketed as long as they include Category I ingredients.

The combination of the two diuretics, ammonium chloride and caffeine, is also logical. This assumption is based on the mechanisms of action of each drug which are different and additive. The panel recommended that any two Category I diuretics could be combined as long as they have different mechanisms of action.

Table 3 lists combinations of active ingredients that may be marketed as OTC menstrual products and indicated for appropriate symptoms.

TABLE 3

Combinations of Active Ingredients Permitted For OTC Menstrual Products*

Analgesic plus Diuretic
Analgesic plus Antihistamine plus Diuretic
Diuretic plus Antihistamine
Two Diuretics**

*Established by an FDA/OTC advisory panel. Each ingredient must be Category I.
**Must have different mechanisms of action.

Patient Advice

The advisory panel noted that individual symptoms of a cluster cannot be stated on product labels unless the drug has been demonstrated to be effective for each of them. In other words, for the label to specifically indicate that the product is effective for cramps, it must also be effective for headache, muscle stiffness, and each of the other components of the pain cluster.

Consumers seeking an OTC product intended for relief of menstrual discomfort should be questioned as to which specific symptoms are being experienced. Appropriate products can then be selected that are tailored to treat those symptoms. If one product fails to provide adequate relief, another one with different ingredients can be tried since they have different mechanisms of action. Table 4 lists representative OTC products, and Table 5 summarizes important information about them.

TABLE 4

Representative OTC Products For Menstrual Disorders

	INGREDIENTS* (mg)							
PRODUCT	**AS**	**AC**	**IB**	**AM**	**CA**	**PA**	**CI**	**PY**
Advil			200					
Aqua-Ban				325	100			
Cope**	421				32			
Dimensyn		500				25		15
Midol	454				32.4		14.9	
Midol Maximum Strength	500				32.4		14.9	
Midol PMS		500				25		15
Nuprin			200					
Pamprin		325				25		12.5
Pamprin Maximum Cramp Relief Formula		500				25		15
Premesyn PMS		500				25		15
Pursettes Premenstrual		500				25		15
Sunril Premenstrual		300				50		25
Trendar		325				25		

*AS: Aspirin; AC: Acetaminophen; IB: Ibuprofen; AM: Ammonium chloride; CA: Caffeine; PA: Pamabrom; CI: Cinnamedrine; PY: Pyrilamine maleate
**Also contains magnesium hydroxide 50 mg, aluminum hydroxide 25 mg.

TABLE 5

Consumer Advice For OTC Menstrual Products

- Keep out of the reach of children.
- In case of accidental overdose, contact a poison control center, emergency medical facility, or physician immediately.
- Do not take this medication for longer than 10 consecutive days.
- This product may be taken with food or milk if it upsets your stomach.
- For products containing pyrilamine maleate: This product may cause drowsiness.
- For products containing ammonium chloride: Do not take this longer than 6 consecutive days. Do not take it if you have liver or kidney disease.
- For products containing caffeine: This product may cause sleeplessness if taken within 4 hours of bedtime.

Besides using OTC products, symptoms of menstruation may be relieved in other ways. These include applying heat to the abdomen and pelvic area or taking hot baths, massage, deep breathing, and bed rest. Drinking hot beverages and restricting sodium intake also helps.

Whenever secondary dysmenorrhea or the premenstrual syndrome is suspected, pharmacists should recommend that the woman consult a physician. Treatment of the underlying disorder is mandatory for any lasting relief.

Timely Topics

This is the fourth in a four part series on osteoporosis. A sample Elder-Ed talk on the subject is outlined to assist and encourage pharmacists to present these issues to the lay public, particularly to older audiences.

Osteoporosis Part IV: Some Unanswered Questions and Directions for Further Studies: Sample Elder-Ed Talk

Madeline Feinberg
Peter P. Lamy

Increased morbidity and mortality associated with osteoporosis, coupled with the growing number of individuals at risk to this disease, has focused national attention on the need to find solutions to some of the unanswered questions with regard to predicting the disease and managing the disease.

According to the N.I.H. Consensus Panel on Osteoporosis, two major areas of research need to be addressed: (1) elucidation of factors which control the development and maintenance of bone as a tissue, and (2) development of methods to prevent and treat the disease.

The panel recommends several approaches that need to be considered:

—epidemiologic studies to look at the demographic and behavioral factors which affect bone mass and fracture rates,

—clinical studies to look at observed difference among patients with the disease to increase ability to predict different responses to treatment,

—development of accurate, inexpensive and safe tests to predict risk for the disease and to measure course of the disease,

—strategies to be applied to population groups at risk to minimize bone loss, maximize bone mass and prevent fractures,

—determination of role of gonadal hormones in bone growth, remodeling and in disease states to develop an optimal/hormonal regimen to prevent bone loss and fracture,

—studies to look at changes in structure and biomechanical properties of bone in disease states and the relationship of these changes to the management of fractures.

Elder-Ed Sample Talk: Osteoporosis

I. Introduction
  A. What does your audience already know: Ask!
    —How many people here take calcium every day?
    —Why did you decide to take calcium?
    —How much do you take daily?
    —Whom did you ask for advice on taking calcium?
    —Does anyone here know someone who has had a fractured hip?

—If so, what happened to them after the fracture?

—Why do older people get fractures?

II. Osteoporosis

A. Define "primary osteoporosis"

—it is related to age

—characterized by a decrease in bone mass ("shrinking" is a very dramatic example, very progressed!)

—with age, increased susceptibility

B. Who is *most* at risk?

—females

—Caucasians

—small-boned

—disease most active within first 10 years after menopause

—affects 15–20 million people in United States

C. Do all older people get osteoporosis?

—all people, with aging, lose bone mass

—including men, non-whites

—everyone must be concerned

D. Consequences of disease

—fractures, immobility, decrease in quality of life

—pain, as result of deformity

III. Diagnosing the problem: How can you tell if you have the disease?

—very difficult to detect

—no simple, quick, and most important *sensitive* test which helps doctor predict if you are getting disease

—diagnosis usually made *after* fracture occurs, or pain sets in

IV. Treatment of the disease

—cannot "cure"

—goal is to prevent further bone loss

—may receive medications or supports to prevent pain and maintain person's mobility

A. Estrogen Replacement

1. currently most effect treatment to prevent further bone loss in women who have had a fracture
2. some women cannot take estrogen because they may be at very great risk to development of uterine cancer
3. estrogen use is associated with increased risk to cancer of uterus (about 3 times the rate as non-estrogen user)
4. "putting things into perspective"

—uterine cancer, in general, not that common (few women get the disease, compared to number of women who will get osteoporosis)

—more sickness and death is associated with disease of osteoporosis than with uterine cancer, particularly when diagnosed at early stage

—if estrogen is prescribed, the patient and the doctor must discuss both alternatives, the patient's individual family and physical history. Patients need to be certain that they understand *all* the risks associated with taking estrogen therapy, and *not* taking estrogen therapy

5. Estrogen use found *NOT* to be associated with increased breast cancer
6. Estrogen may have some benefit for post-menopausal women by protecting against cardiovascular disease: *NOT* proven yet
7. Many unanswered questions remain regarding estrogen use:

—how much to prescribe?

—for how long to prescribe?

—when to start?

8. Most important! Estrogen use is recommended as treatment for osteoporosis.

—many doctors may chose to put their patients on estrogen therapy without signs of the disease. These may be patients whom doctor feels are at special risk to the disease

—be certain you understand *exactly* why your doctor recommends, or does *not* recommend, estrogen therapy for you. Ask what the "goal" of your treatment plan is!

B. Use of Progestin in combination with estrogen

1. Appears that progestin given for last 5 days of estrogen use (25 days on estrogen, 5 days off) is becoming more popular.
2. Progestin may reduce risk of uterine cancer, but other potential risks are not yet known.

V. Prevention of Osteoporosis

A. Role of calcium "stuff bones are made of" (from F.D.A. Consumer)

1. Dietary inadequacy

—majority of Americans use less than RDA of calcium (explain RDA)

—RDA = "recommended daily allowance to prevent evidence of deficiency in most healthy adults"

—current RDA for calcium is 800 mg elemental calcium

—Too low!

—Current belief: 1,000 mg elemental calcium for pre-menopausal women
1,500 mg elemental calcium for post-menopausal women

2. Bone loss begins at early age, perhaps 25 years in female
3. Need to have adequate calcium in diet during *all* of adult life!

B. How much calcium supplement is enough?

1. Depends on dietary intake
2. Sources of calcium in diet: on *daily* basis

—dairy products excellent source

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  - —but many do not eat because of cholesterol content, calories, lactose intolerance
3. Daily calcium intake must add up to 1,000 mg (premenopausal) and for 1,500 mg postmenopausal women. (Men should take 1,000 mg daily throughout adult life)
   - —deduct dietary intake from suggested amount noted, then take rest as supplement
   - —your pharmacist should help you select the right product and recommend the correct dosage to take
   - —important to understand that it is ''elemental calcium'', not total amount of calcium product:
   - —contrast amount of calcium in calcium carbonate (40%)
     calcium in calcium lactate (13%)
     calcium in calcium gluconate (9%)
4. Choice of products
   - —high costs
   - —need to be certain product you select will dissolve (some do not) (drop in glass of water, wait 30 minutes)
   - —check with pharmacist who can recommend product
   - —''natural'' products may contain unacceptably high amounts of magnesium, or other trace minerals such as lead or arsenic. Need to be careful
   - —antacids are NOT all calcium-containing products. Do not select without pharmacist assistance. Only certain antacids contain calcium.

C. Role of Vitamin D
1. needed to help calcium to absorbed
2. source is sunlight and fortified dairy products
3. need to avoid excess Vit. D. May be toxic!
4. Bedbound, homebound, may need to take Vit. D. supplement. Check with doctor. Know other vitamins person may be taking!

D. Other minerals
1. Sodium fluoride: Only prescribed by doctor, Rarely used,
   - —may help bone grow, but growth patterns not normal
   - —associated with many side effects
2. Zinc—not proven to have any role in prevention or treatment of disease. If taken in excess, may interfere with absorption of calcium and other essential minerals

E. ''Exercise''
- —''activity'' a better word
- —walking is best
- —weight-bearing activity important (effects of gravity important in healthy bone)
- —if walking not possible, individuals should discuss with their doctor who can recommend alternative activities to keep bone healthy
- —''Use it or lose it!''

VI. Conclusion
- —much is still unknown about disease
- —methods to prevent include adequate dietary intake and activity within reasonable limits
- —discuss prevention with your doctor to be certain he/she is aware of your interest and concerns about this serious disease.

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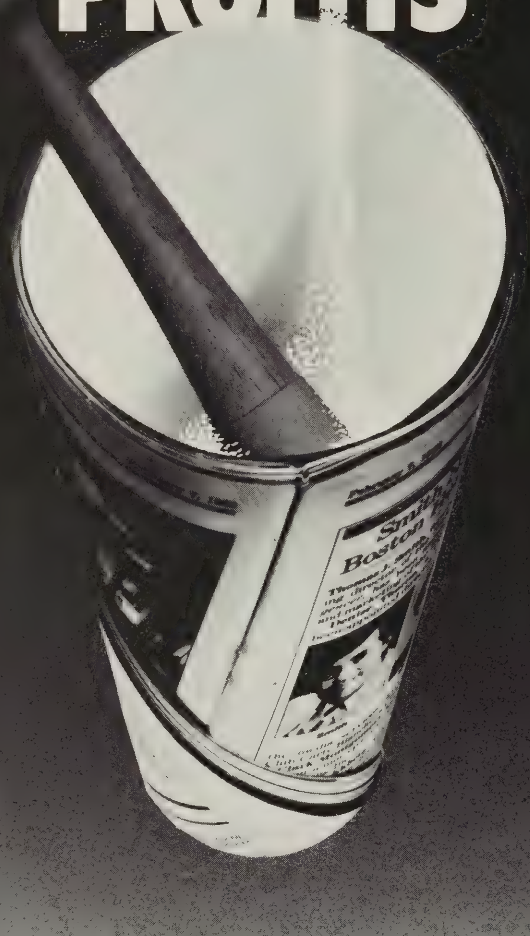

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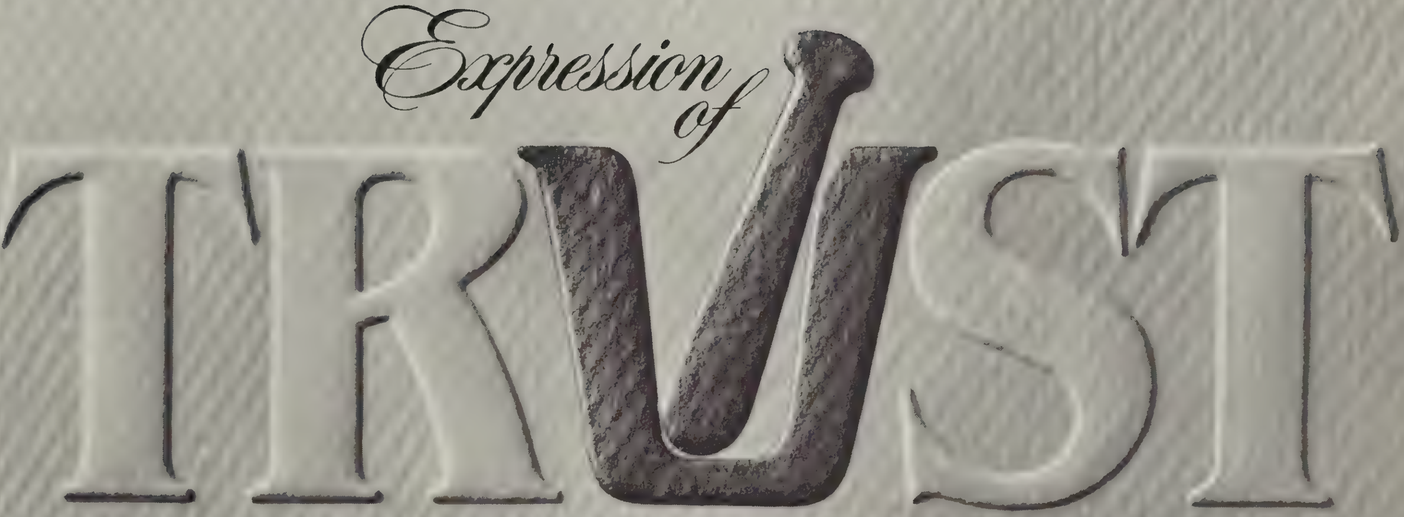

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Spinning on stools allowed

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By Dolly Merritt
Contributing writer

It's 10 a.m. and the coffee's hot as the neighborhood regulars slide onto stools at the soda fountain and talk about the latest S&L developments.

Sixty-one-year-old Lydia "Lee" M. Ball is getting ready to deliver prescriptions and Donald "Doc" J. Dagold advises an elderly man about the dangers of mixing medications.

This old-fashioned scene is all in a day's work for Mr. Dagold, who lives in Baltimore County and who opened the Watermont Pharmacy in Ellicott City 25 years ago. The good old days still live on at the drugstore from 8:30 a.m. to 8 p.m. Monday through Saturday. It is one of five businesses located in a cul de sac off Routes 103 and 104.

"I've resisted changing to computers," said the 52-year-old pharmacist and owner of the establishment. "It's very comfortable here . . . The customers are pleasant, and I know the majority by name."

As a matter of fact, Mr. Dagold's personal interest in people is what prompted him to open his business in a sparsely-populated area. "I liked the idea of a neighborhood store," Mr. Dagold said.

In 1961, the neighborhood consisted of a few houses scattered along Routes 103 and 104, formerly Montgomery and Waterloo roads. Two housing developments, Stonecrest and Montgomery Knolls, were new additions to the mostly rural area.

"Two of my business friends told me, 'I'll give you a year [for the business to fold]," Mr. Dagold said. Today, four more housing developments later, the Watermont Pharmacy is still in business and remains a neighborhood store.

The Watermont staff consists of two pharmacists, three women who tend the soda fountain and make deliveries and two teen-age boys who stock shelves and run errands. In addition, Mr. Dagold's wife, Audrey, works in the store three days a week.

The couple's four grown daughters have each worked in the store also. "We have no specialists here. Everyone does a little bit of everything," Mr. Dagold said.

On one weekday morning, the newest employee, Patsy M. Voland, continued to pour coffee for the steady stream of people who came to exchange conversation over a cup of coffee. Frequently she would leave her post at the soda fountain to ring up a loaf of bread or a bottle of aspirins at the cash register.

A neighborhood resident herself, the 54-year-old woman chatted amiably with the customers. Mrs. Voland has been working at the pharmacy three days a week since November.

"I come in contact with a lot of nice people," she said. "Everybody is friendly and a lot of the customers are my neighbors."

One neighbor, Richard J. Muirhead, who lives next to the small strip of businesses, has helped Mr. Dagold and his employees on several occasions.

"He's helped the girls get their cars out of the snow, he repairs things and I slept in his house during one snowstorm when I couldn't get home," Mr. Dagold said.

"If there's a drugstore equivalent to a country store, this is it," said Mr. Muirhead, who visits the business twice a day. The 69-year-old retired government employee has frequented the establishment since its opening in 1961 and has three grown sons who "started their business careers" by working part-time for Mr. Dagold.

"I come to talk with the boys and get a cup of coffee," said another regular, Mead F. Jestes Sr. The 75-year-old former security guard also lives close by and is a veteran customer.

"Doc will do anything to help people and will call elsewhere if he doesn't have it here," Mr. Jestes said.

Another neighborhood member of the coffee klatch is John A. Meisel, a 61-year-old retired government employee. "It's a meeting place here. We sit and have coffee while we talk over community affairs . . . They always keep the coffee hot and fresh," Mr. Meisel said.

Lydia Ball, long-time employee who has kept the coffee hot for 22 years, is a friend to most of the morning crowd. The customers teased her good-naturedly, and she responded with a smile.

Through the years, Mrs. Ball's favorite part of the job is her contact with people. "I like people," she said. "They're in and out of here all the time."

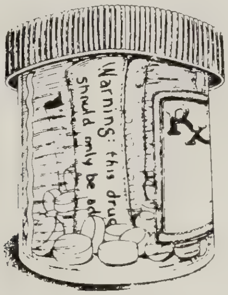
"Where's Dora?" asked Howard E. Huber, a 59-year-old chemist who lives "up the street." Mr. Huber described Dora M. Deavers, another Watermont veteran employee, as being "the best milkshake maker in the county." The chemist said he frequents the establishment three or four times a week because of "pretty waitresses, fresh coffee and cigarettes."

The notorious milkshake maker is 76 years old and has been working at the pharmacy for about 16 years. Like her co-workers, Mrs. Deavers makes cherry Cokes, snowballs with fountain flavors and milkshakes with real milk.

When asked what part of her job she liked most, she said, "I like anything. It doesn't make any difference, I'll do it . . . I make deliveries during rain, hail, snow and sunshine."

That same spirit of willingness is what prompted Mr. Dagold to install a blood pressure machine for the benefit of his customers.

The pharmacist also had his younger customers in mind when he installed short stools at the soda fountain "so youngsters could reach the counter. Kids like to spin on those stools," he said.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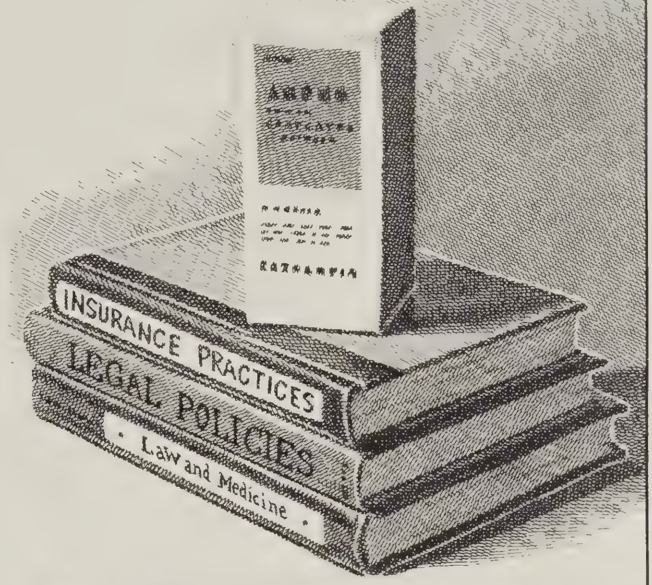

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Two Views of the Grass Roots 21 Conference

by Evelyn Farinas

Grass Roots 21 Conference was a natural follow up to the historical assembly which met at Millwood, VA in 1984 to discuss pharmacy in the 21st century. Two years ago pharmacists from all areas of practice met to create future scenarios in order to design ways in which the profession could grow in order to meet the demands of the next century. Using the findings of this conference as a background, participants at Grass Roots 21, representing seven eastern states plus the District of Columbia, were charged with formulating plans to be implemented now before the 21st century; that is to take action in shaping the future as opposed to reacting to changes imposed on pharmacy by other forces such as government regulations, cost containment, etc.

The conference organized by the Maryland and Virginia Pharmaceutical Associations followed a workshop format of 4 sessions:

A–Pharmacy education
B–Ethics of health care
C–Survival of the independent pharmacy
D–New/non traditional roles for pharmacy: profession or business

Two trends of our society were identified as major forces changing the future of health care: the aging of

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Pharmacy in the 21st Century
Planning for an uncertain future
May 3, 1986

by Richard Reitz

How do you imagine the practice of pharmacy will be like in 25 years? One informed opinion suggests that the routine tasks of dispensing might be performed by computers and robots. Also, practitioners would have at their disposal a system of communications which would allow complete access to a patient's medical record. Pharmacists would be free to perform problem solving and interpersonal tasks (those requiring judgement, creativity and empathy).

A meeting of pharmacy practitioners was held in Crystal City, Virginia, on May 3, 1986 to discuss the future of pharmacy based on the findings of the "Pharmacy in the 21st Century" Conference. This name of this conference was "Grass Roots 21."

A wrap-up of the Grass Roots 21 conference was presented by Douglas Hepler of the Medical College of Virginia. His wrap-up was a synthesis of his own views along with a summary of proceedings of Grass Roots 21. Hepler saw the future of pharmacy (and specifically ethics, markets, education and new professional roles) being influenced by three major forces: technological innovations, social forces and economics.

Technological innovations such as computers, robots, and new therapies and delivery systems were viewed as the factors through which technology would have an impact on pharmacy practice.

the baby boomers, and the shift towards the political right. The implications are an increased demand for services, yet at the same time the federal government is trying to shift the responsibility of health care to state and local agencies. It was predicted that in the near future there will be only 20 major hospital corporations in control of health care in this country. Business corporations in order to trim costs will determine the extent of services that a patient will receive, and where will these services be rendered.

To meet future changes, pharmacy educators must modify their curriculums so that actual practitioners can evolve into the new roles foreseen by the participants. New technologies such as new drug delivery systems, make it mandatory for pharmacy schools to stress basic sciences. At the same time it is perceived that in the midst of the increased technological society of the future consumers will demand more information and the pharmacist should receive increased training in clinical areas, communication skills, management of health care economics, etc. Perhaps the answer lies in creating a program which will result in awarding only one type of entry level degree (not a B.S. vs a Phar. D) and then continue into areas of specialty.

As technology evolves and the dollar shrinks, ethical questions of accessibility to health care will plague every practitioner in the health care fields. Nowadays the best care is available to the very poor, thru federally subsidized programs, or to the very rich for whom expense is not a hardship. Future projections describe a society where major corporations will determine who will receive, and where and how much care is available to its employees. The providers of care, be it physicians, pharmacist, nurses, etc will work for the corporation, and may have to decide at some point to whom do they owe their loyalty. Perhaps based on today's youth who as a whole is less altruistic, the consensus was that in the future economics will shape ethics.

Medical supermarkets were defined as a setting which includes multiple medical services at one ambulatory site. The premise was that in such a setting the independent practitioner (the corner drugstore) will cease to exist. Interestingly a new concept emerged, that is, the idea that independent practice does not have to go hand in hand with a solo practice. Independent practice should be synonymous with decision making not with who pays the rent. In the years to come pharmacists should strive to get reimbursed for the services offered, independently from the cost of the medications. In order to attain that practitioners have to redefine their roles and use technological advances to enhance their usefulness to the community they serve, be that the public at large, hospital administrators, or large corporations.

Pharmacy was seen as a profession evolving into 2 primary roles: as advisor of drug utilization, and as dispenser of highly specialized and individualized dosage forms. To allow practitioners a comfortable expansion

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Communicating computer systems are envisioned which could provide interconnected information pathways between medical institutions, groups and solo practitioners (and even the patient). This would allow all participants in the health care system to have access to the same information about their patients. This communication of health information could also be achieved through the use of a 'smart card' such as the Lifecard.

Robots have already been proposed and built which can perform simple pharmacy tasks above and beyond the Brewer machines and Baker cells with which we are familiar.

New drug therapies and delivery systems are currently being developed which will greatly change the current practice of medicine and pharmacy. It has been suggested that most current pharmaceuticals (antibiotics, steroids, NSAIDs) are the result of the first pharmacological revolution. We are now at the dawn of the second pharmacological revolution and it will see the development of new drugs which include immunoregulators.

New drug delivery systems are currently being developed for which the role of the pharmacist is uncertain. These developments include single dose long acting forms (tablets, transdermal patches, subcutaneous tablets, etc) which could be administered in a physician's office or a setting other than a pharmacy.

It was pointed out that it is important to remember that technology must have a human face (be processed by a human being) in order to be most useful and receive public acceptance. This leads us into the impact of social forces on the future.

Social Forces which will impact the profession include the following:

Demographics (especially the aging of the population)
Social Cost vs. Social Benefit (health care for the extremely old?; Instead of health at any cost, the goal is shifting to health at reasonable cost)
Group Rights vs. Individual Freedom (such issues as smoking in public)
Influences on Behavior (having good character vs. just following the rules)
Corporate Practice of Health Professions (HMOs!; This is influenced by ethics, the individuals sense of values and the knowledge of how corporations behave and make decisions)
The Meaning of Work

The economic forces which will dominate health care and the profession are comprised of the following three "C's":

Capitation (for services)
Comprehensive (care)
Concentration (of providers and markets

into these roles, pharmacy education must start now to develop ways in which pharmacy graduates of longer standing can acquire the necessary skills. However an exact mechanism to do this was not outlined in the conference.

Dr. Douglas Hepler summarized the proceedings stating there are 3 forces which will shape the future:

Technological forces: computers, robots, new individualized drug therapies

Social forces: demographic changes; group rights vs. individual freedom; who/what determines the allocations of health resources.

Economic forces: capitation; concentration of buyers and sellers of health care; corporations contracted health care services.

Pharmacists will have to deal with 2 issues: image and competence. Pharmacists must project an image of usefulness—for instance, proper drug monitoring will shorten a patient's stay in the hospital—in order to get reimbursed for services. And in the midst of a highly technological futuristic society, pharmacists must really have the knowledge, skills, and the compassions to show that we are really as competent as we have claimed to be all along.

To these were added two more "C's:" Corporations and Contracts. These are influencing factors or characteristics of the other three.

The new business of health care which will be paid for through prospective payment. No longer will a practitioner profit in providing inefficient care. It will become important to the health care manager to push the patients to the right in the following plan:

Intensive > Acute > Home > Ambulatory > Wellness
Care Care Care Care

We are asked to answer the following questions in order to determine the future of pharmacy:

1. Will HMOs see pharmacy as a necessary component of care or as overhead?
2. Can the profession provide enough competent pharmacists to fulfill its perceived mission? (Competence = knowledge, skill and the right attitude or professional ideology)

It has been suggested that pharmacists (as well as other professionals) are allowed to thrive only to the extent that they serve the needs of society. Thus, the issues of image (public and self) and competence are basic to the determination of the role of pharmacy in the next 25 years.

Pharmacists

The Medic Alert *Emblem* (bracelet or necklet) is the TRIGGER that activates the emergency medical information system. Anywhere in the world, anytime of the day or night, medical personnel need only call Medic Alert's *24-hour hotline* and provide a patient's I.D. number engraved on the emblem. Within 30 seconds, information from the *computerized emergency medical file* can be provided to assist in treatment. In addition, each member has a *wallet card* and the Foundation initiates an annual update procedure. Members, however, can update information at any time.

The National Task Group during its special session presentation at the Convention emphasized that Medic Alert integrates the full circle of medical protection encompassing the patient, physician, hospital and pharmacist. Moreover, Medic Alert has developed special materials for the pharmacist and provides them at no cost upon request. The kit includes:

1. Front window poster (full color) to announce your pharmacy's involvement in this program.
2. Counter application holder with applications to be permanently placed for convenience of the patient near point of sale.
3. Medic Alert Reference Guides (2)
   - —One to be posted in the work area to highlight conditions covered by Medic Alert protection
   - —One to be placed at the point of sale for your staff and patients.
4. Stuffers to be inserted into all prescription bags for patients you believe could benefit from Medic Alert protection or to be used as a shelf talker.
5. Response card to be returned indicating participation in the pharmacist's program and ordering additional materials.

The materials for this project are underwritten by a grant from Stuart Pharmaceuticals, Division of ICI Americas Inc.

These new pharmacy materials are being mailed to all pharmacies. If you have not received your materials by April 10th, please call Medic Alert Foundation International's Field Services Division, 1-800-344-3226 (In Alaska call 1-209-668-3333.)

Can Make the Difference

The National Pharmacy Task Group, in collaboration with Medic Alert Foundation, unveiled a pharmacist-to-patient education program featuring Medic Alert's service at the American Pharmaceutical Association's March Convention in San Francisco.

Because of the potential seen in establishing a cooperative program between pharmacists and Medic Alert, the National Pharmacy Task Group was recently created to develop a program through which pharmacists can expedite efficient emergency medical care, demonstrate that their care protects the health of their patients, and build patient loyalty, all at no cost to the pharmacist. By recommending Medic Alert's service, pharmacists can have a positive influence on the lives and health of their patients.

Medic Alert is the only nonprofit organization soley devoted to providing a professional emergency medical identification service for people with conditions that could put them at risk in emergency situations.

A series of 1985 surveys and research projects demonstrate clearly that Medic Alert aids cost-effective patient treatment. Today, Medic Alert is the only internationally recognized emergency medical data system that provides busy emergency personnel with vital patient information quickly, accurately, in one place and on time.

Survey and research information show that:

- One in four Americans has a medical condition that should be immediately known in an emergency.
- Over 13,000 emergency room cases every day in this country are complicated by a lack of accurate and accessible medical information.
- Over 95% of physicians who know Medic Alert say it can save lives.
- 3% of Medic Alert members say their lives have been saved by Medic Alert.
- 21% of members reported learning from medical professionals that Medic Alert service saved time in emergency room treatment.
- 20% reported learning from medical professionals that Medic Alert assisted in accurate diagnosis.

While various competitors have bracelets, cards and micro fiche, no other organization provides the worldwide comprehensive health protection system that Medic Alert provides.

GET A PRESCRIPTION FOR LIFE

Above (from right) Richard Haggard, National Field Director for Medic Alert; Robert Johnson, Executive Vice President of the California Pharmacists Association and Chairman of the National Pharmacy Task Group; Kenneth Harms, President of Medic Alert; and Joel Tau, Manager of Professional Affairs for Stuart Pharmaceuticals, view part of the National Pharmacy Kit for the program.

22,000 Items.
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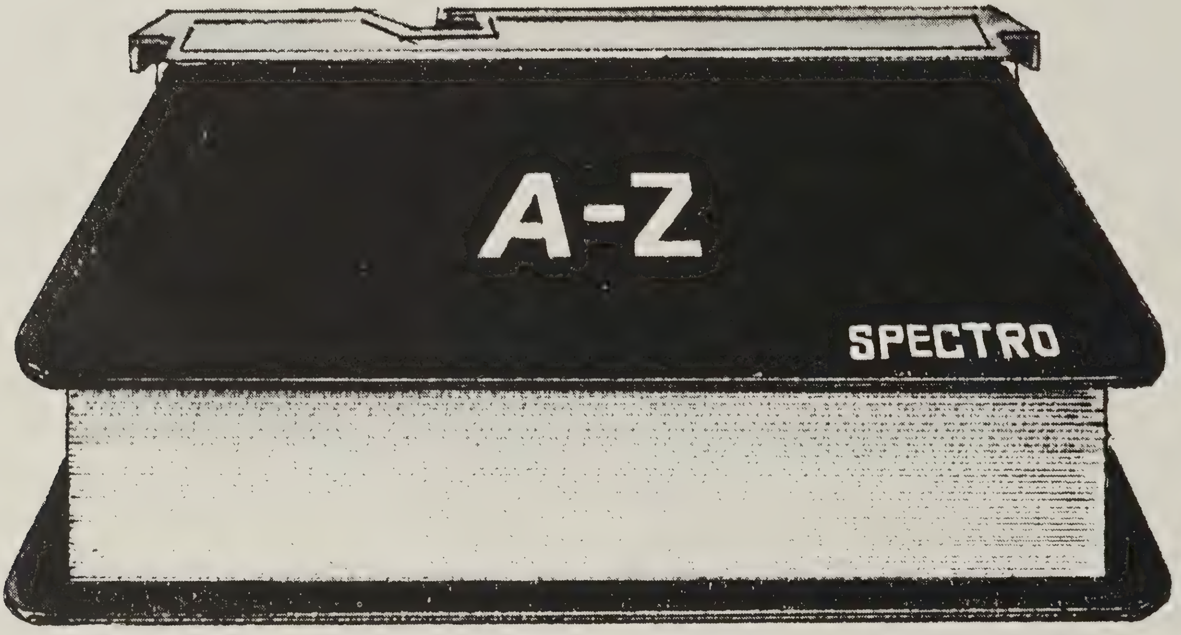

You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

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Insurance Checklist for Small Business

By Mark R. Greene*

Summary

There may be ways of strengthening your insurance program that have not occurred to you. The purpose of this paper is to help you find out. To this end, a checklist is provided that will help you identify areas in which improvement may be possible. It will also serve as a guide for the discussions you should have with a qualified agent, broker, or other insurance counselor.

The points covered are grouped under three general heads: coverages that are essential for most businesses; coverages that are desirable for many firms but not absolutely necessary; and coverages for employee benefits.

The checklist is followed by a brief discussion of four basic steps that are necessary for good insurance management: (1) Recognize the risks to which you are exposed. (2) Follow the guides for buying insurance economically. (3) Have a plan. (4) Get professional advice.

Some small businessmen look on insurance as if it were a sort of tax. They recognize that it is necessary but consider it a burdensome expense that should be kept at a minimum. Is this view justified?

Not if you take a more constructive approach. You can use insurance to get many positive advantages as well as the negative one of avoiding losses. Used correctly, insurance can contribute a great deal to your success by reducing the uncertainties under which you operate. It can reduce employee turnover, improve your credit at the bank, make it easier to sell to customers on favorable terms, help keep your business going in case an insured peril interrupts operations. The potential benefits of good insurance management make it well worth your study and attention.

How It Works

Insurance has been defined as a system in which "winners pay losers." Those who are lucky enough to avoid loss contribute through premium payments to the unlucky ones who do suffer loss. If you never collect from your insurance, consider yourself ahead, because then you are one of the winners. If you suffer a loss for which you are insured, you have the security of knowing that the other members of the insurance system will relieve you of most of your burden.

In this sense, you come out ahead either way. Your premiums are the price you pay for freedom from worry about economic loss from conditions outside your control.

But insurance itself becomes the subject of worry for many small businessmen. This paper is designed to help you lessen this worry.

Essential Coverages

Four kinds of insurance are essential: *fire insurance, liability insurance, automobile insurance,* and *workers' compensation insurance*. In some areas and in some kinds of businesses, crime insurance, which is discussed under "Desirable Coverages," is also essential.

Are you certain that all the following points have been given full consideration in your insurance program?

Fire Insurance

1. You can add other perils—such as windstorm, hail, smoke, explosion, vandalism, and malicious mischief—to your basic fire insurance at a relatively small additional cost.

2. If you need comprehensive coverage, your best buy may be one of the all-risk contracts that offer the broadest available protection for the money.

3. The insurance company may idemnify you—that is, compensate you for your losses—in any one of several ways: (1) It may pay actual cash value of the property at the time of loss. (2) It may repair or replace the property with material of like kind and quality. (3) It may take *all* the property at the agreed or appraised value and reimburse you for your loss.

4. You can insure property you don't own. You must have an insurable interest—a financial interest—in the property *when a loss occurs* but not necessarily at the time the insurance contract is made. For instance, a repair shop or drycleaning plant may carry insurance on customers' property in the shop, or a person holding a mortgage on a building may insure the building although he doesn't own it.

5. When you sell property, you cannot assign the insurance policy along with the property unless you have permission from the insurance company.

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* Distinguished Professor of Insurance, University of Georgia, Athens, Georgia 30601.

6. Even if you have several policies on your property, you can still collect only the amount of your actual cash loss. All the insurers share the payment proportionately. Suppose, for example, that you are carrying two policies—one for $20,000 and one for $30,000—on a $40,000 building, and fire causes damage to the building amounting to $12,000. The $20,000 policy will pay $4,800; that is, $\frac{20,000}{50,000}$, or $\frac{2}{5}$, of $12,000. The $30,000 policy will pay $7,200; which is $\frac{30,000}{50,000}$, or $\frac{3}{5}$, of $12,000.

7. Special protection other than the standard fire policy is needed to cover the loss by fire of accounts, bills, currency, deeds, evidences of debt, and money and securities.

8. If an insured building is vacant or unoccupied for more than 60 consecutive days, coverage is suspended unless you have a special endorsement to your policy canceling this provision.

9. If, either before or after a loss, you conceal or misrepresent to the insurer any material fact or circumstance concerning your insurance or the interest of the insured, the policy may be voided.

10. If you increase the hazard of fire, the insurance company may suspend your coverage even for losses not originating from the increased hazard. (An example of such a hazard might be renting part of your building to a drycleaning plant.)

11. After a loss, you must use all reasonable means to protect the property from further loss or run the risk of having your coverage canceled.

12. To recover your loss, you must furnish within 60 days (unless an extension is granted by the insurance company) a complete inventory of the damaged, destroyed, and undamaged property showing in detail quantities, costs, actual cash value, and amount of loss claimed.

13. If you and the insurer disagree on the amount of loss, the question may be resolved through special appraisal procedures provided for in the fire-insurance policy.

14. You may cancel your policy without notice at any time and get part of the premium returned. The insurance company also may cancel at any time with a 5-day written notice to you.

15. By accepting a coinsurance clause in your policy, you get a substantial reduction in premiums. A coinsurance clause states that you must carry insurance equal to 80 or 90 percent of the value of the insured property. If you carry less than this, you cannot collect the full amount of your loss, even if the loss is small. What percent of your loss you can collect will depend on what percent of the full value of the property you have insured it for.

16. If your loss is caused by someone else's negligence, the insurer has the right to sue this negligent third party for the amount it has paid you under the policy. This is known as the insurer's right of subrogation. However, the insurer will usually waive this right upon request. For example, if you have leased your insured building to someone and have waived your right to recover from the tenant for any insured damages to your property, you should have your agent request the insurer to waive the subrogation clause in the fire policy on your leased building.

17. A building under construction can be insured for fire, lightning, extended coverage, vandalism, and malicious mischief.

Liability Insurance

1. Legal liability limits of $1 million are no longer considered high or unreasonable even for a small business.

2. Most liability policies require you to notify the insurer immediately after an incident on your property that might cause a future claim. This holds true no matter how unimportant the incident may seem at the time it happens.

3. Most liability policies, in addition to *bodily* injuries, may now cover *personal* injuries (libel, slander, and so on) *if* these are specifically insured.

4. Under certain conditions, your business may be subject to damage claims even from trespassers.

5. You may be legally liable for damages even in cases where you used "reasonable care."

6. Even if the suit against you is false or fraudulent, the liability insurer pays court costs, legal fees, and interest on judgments *in addition to* the liability judgments themselves.

7. You can be liable for the acts of others under contracts you have signed with them. This liability is insurable.

8. In some cases you may be held liable for fire loss to property of others in your care. Yet, this property would normally not be covered by your fire or general liability insurance. This risk can be covered by fire legal liability insurance or through requesting subrogation waivers from insurers of owners of the property.

Automobile Insurance

1. When an employee or a subcontractor uses his own car on your behalf, you can be legally liable even if you don't own a car or truck yourself.

2. Five or more automobiles or motorcycles under one ownership and operated as a fleet for business purposes can generally be insured under a low-cost fleet policy against both material damage to your vehicle and liability to others for property damage or personal injury.

3. You can often get deductibles of almost any amount—say $250 or $500—and thereby reduce your premiums.

4. Automobile medical-payments insurance pays

for medical claims, including your own, arising from automobile accidents regardless of the question of negligence.

5. In most States, you must carry liability insurance or be prepared to provide other proof (surety bond) of financial responsibility when you are involved in an accident.

6. You can purchase uninsured-motorist protection to cover your own bodily-injury claims from someone who has no insurance.

7. Personal property stored in an automobile and not attached to it (for example, merchandise being delivered) is not covered under an automobile policy.

Worker's Compensation

1. Common law required that an employer (1) provide his employees a safe place to work, (2) hire competent fellow employees, (3) provide safe tools, and (4) warn his employees of an existing danger.

2. If an employer fails to provide the above, under both common law and workers' compensation laws he is liable for damage suits brought by an employee.

3. State law determines the level or type of benefits payable under workers' compensation policies.

4. Not all employees are covered by workers' compensation laws. The exceptions are determined by State law and therefore vary from State to State.

5. In nearly all States, you are now legally *required* to cover your workers under workers' compensation.

6. You can save money on workers' compensation insurance by seeing that your employees are properly classified.

7. Rates for workers' compensation insurance vary from 0.1 percent of the payroll for "safe" occupations to about 25 percent of more of the payroll for very hazardous occupations.

8. Most employers in most States can reduce their workers' compensation premium cost by reducing their accident rates below the average. They do this by using safety and loss-prevention measures.

Desirable Coverages

Some types of insurance coverage, while not absolutely essential, will add greatly to the security of your business. These coverages include business-interruption insurance, crime insurance, glass insurance, and rent insurance.

Business Interruption Insurance

1. You can purchase insurance to cover fixed expenses that would continue if a fire shut down your business—such as salaries to key employees, taxes, interest, depreciation, and utilities—as well as the profits you would lose.

2. Under properly written contingent business-interruption insurance, you can also collect if fire or other peril closes down the business of a supplier or customer and this interrupts your business.

3. The business-interruption policy provides payments for amounts you spend to hasten the reopening of your business after a fire or other insured peril.

4. You can get coverage for the extra expenses you suffer if an insured peril, while not actually closing your business down, seriously disrupts it.

5. When the policy is properly endorsed, you can get business-interruption insurance to indemnify you if your operations are suspended because of failure or interruption of the supply of power, light, heat, gas, or water furnished by a public utility company.

Crime Insurance

1. Burglary insurance excludes such property as accounts, fur articles in a showcase window, and manuscripts.

2. Coverage is granted under burglary insurance only if there are visible marks of the burglar's forced entry.

3. Burglary insurance can be written to cover, in addition to money in a safe, inventoried merchandise and damage incurred in the course of a burglary.

4. Robbery insurance protects you from loss of property, money, and securities by force, trickery, or threat of violence on *or off* your premises.

5. A comprehensive crime policy written just for small businessmen is available. In addition to burglary and robbery, it covers other types of loss by theft, destruction, and disappearance of money and securities. It also covers thefts by your employees.

6. If you are in high-risk area and cannot get insurance through normal channels without paying excessive rates, you may be able to get help through the federal crime insurance plan. Your agent or State Insurance Commissioner can tell you where to get information about these plans.

Glass Insurance

1. You can purchase a special glass-insurance policy that covers all risk to plate-glass windows, glass signs, motion-picture screens, glass brick, glass doors, showcases, countertops and insulated glass panels.

2. The glass-insurance policy covers not only the glass itself, but also its lettering and ornamentation, if these are specifically insured, and the costs of temporary plates or boarding up when necessary.

3. After the glass has been replaced, full coverage is continued without any additional premium for the period covered.

Rent Insurance

1. You can buy rent insurance that will pay your rent if the property you lease becomes unusable be-

cause of fire or other insured perils and your lease calls for continued payments in such a situation.

2. If you own property and lease it to others, you can insure against loss if the lease is canceled because of fire and you have to rent the property again at a reduced rental.

Employee Benefit Coverages

Insurance coverages that can be used to provide employee benefits include group life insurance, group health insurance, disability insurance, and retirement income. Key-man insurance protects the company against financial loss caused by the death of a valuable employee or partner.

Group Life Insurance

1. If you pay group-insurance premiums and cover all employees up to $50,000, the cost to you is deductible for Federal income-tax purposes, and yet the value of the benefit is not taxable income to your employees.

2. Most insurers will provide group coverages at low rates even if there are 10 or fewer employees in your group.

3. If the employees pay part of the cost of the group insurance, State laws require that 75 percent of them must elect coverage for the plan to qualify as group insurance.

4. Group plans permit an employee leaving the company to convert his group-insurance coverage to a private plan, at the rate for his age, without a medical exam if he does so within 30 days after leaving his job.

Group Health Insurance

1. Group health insurance costs much less and provides more generous benefits for the worker than individual contracts would.

2. If you pay the entire cost, individual employees cannot be dropped from a group plan unless the entire group policy is canceled.

3. Generous programs of employee benefits, such as group health insurance, tend to reduce labor turnover.

Disability Insurance

1. Workers' compensation insurance pays an employee only for time lost because of work injuries and work-related sickness—not for time lost because of disabilities incurred off the job. But you can purchase, at a low premium, insurance to replace the lost income of workers who suffer short-term or long-term disability not related to their work.

2. You can get coverage that provides employees with an income for life in case of permanent disability resulting from work-related sickness or accident.

Retirement Income

1. If you are self-employed, you can get an income tax deduction for funds used for retirement for you and your employees through plans of insurance or annuities approved for use under the Employees Retirement Income Security Act of 1974 (ERISA).

2. Annuity contracts may provide for variable payments in the hope of giving the annuitants some protection against the effects of inflation. Whether fixed or variable, an annunity can provide retirement income that is guaranteed for life.

Key-Man Insurance

1. One of the most serious setbacks that can come to a small company is the loss of a key man. But your key man can be insured with life insurance and disability insurance owned by and payable to your company.

2. Proceeds of a key-man policy are not subject to income tax, but premiums are not a deductible business expense.

3. The cash value of key-man insurance, which accumulates as an asset of the business, can be borrowed against and the interest and dividends are not subject to income tax as long as the policy remains in force.

Organizing Your Insurance Program

A sound insurance protection plan is just as important to the success of your business as good financing, marketing, personnel management, or any other business function. And like the other functions, good risk and insurance management is not achieved by accident, but by organization and planning. A lifetime of work and dreams can be lost in a few minutes if your insurance program does not include certain elements. To make sure that you are covered, you should take action in four distinct ways:

1. Recognize the various ways you can suffer loss.
2. Follow the guides for buying insurance economically.
3. Organize your insurance-management program.
4. Get professional advice.

Recognize the risks. The first step toward good protection is to recognize the risks you face and make up your mind to do something about them. Wishful thinking or an it-can't-happen-to-me attitude won't lessen or remove the possibility that a ruinous misfortune may strike your business.

Some businesses will need coverages not mentioned in the checklist. For example, if you use costly professional tools or equipment in your business, you may need special insurance covering loss or damage to the equipment and/or business interruption resulting from not being able to use the equipment.

Study insurance costs. Before you purchase insurance, investigate the methods by which you can reduce the costs of your coverage. Be sure to cover the following points:

1. Decide what perils to insure against and how much loss you might suffer from each.
2. Cover your largest loss exposure first.
3. Use as high a deductible as you can afford.
4. Avoid duplication in insurance.
5. Buy in as large a unit as possible. Many of the "package policies" are very suitable for the types of small businesses they are designed to serve, and often they are the only way a small business can get really adequate protection.
6. Review your insurance program periodically to make sure that your coverage is adequate and your premiums as low as possible consistent with sound protection.

Have a plan. To manage your insurance program for good coverage at the lowest possible cost, you will need a definite plan that undergirds the objectives in your business. Here are some suggestions for good risk and insurance management:

1. Write down a clear statement of what you expect insurance to do for your firm.
2. Select only one agent to handle your insurance. Having more than one may spread and weaken responsibility.
3. If an employee or partner is going to be responsible for your insurance program, be sure he understands his responsibility.
4. Do everything possible to prevent losses and to keep those that do occur as low as possible.
5. Don't withhold from your insurance agent important information about your business and its exposure to loss. Treat your agent as a professional helper.
6. Don't try to save money by underinsuring or by not covering some perils that could cause loss, even though you think the probability of their occurring is very small. If the probability of loss is really small, the premium will also be small.
7. Keep complete records of your insurance policies, premiums paid, losses, and loss recoveries. This information will help you get better coverage at lower costs in the future.
8. Have your property appraised periodically by independent appraisers. This will keep you informed as to just what your exposures are, and you will be better able to prove what your actual losses are if any occur.

Get professional advice about your insurance. Insurance is a complex and detailed subject. A professionally qualified agent, broker, or consultant can earn his fees many times over.

For Further Information

Readers who wish to explore this subject further may consult the following references. The list is necessarily brief, and no slight is intended toward authors whose works are not mentioned.

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Risk and Insurance, by Mark R. Greene. 3d ed. 1973. South-Western Publishing Co., 5101 Madison Rd., Cincinnati, Ohio 45227.

Insurance and Risk Management for Small Business, by Mark R. Greene. SBMS No. 30. Small Business Administration. 2d ed. 1970. For current price, write to Superintendent of Documents, Washington, D.C. 20402.

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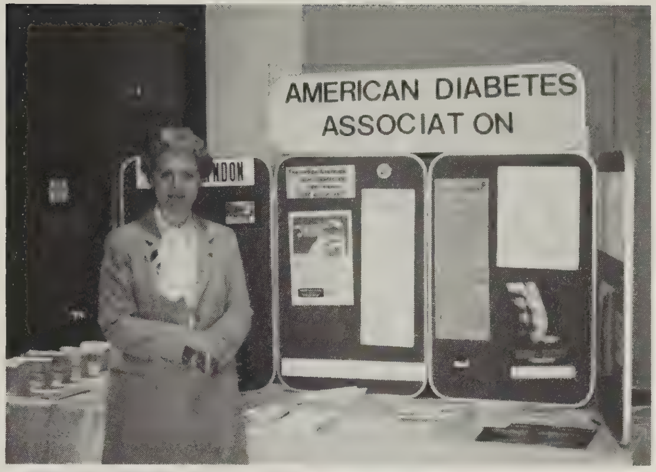
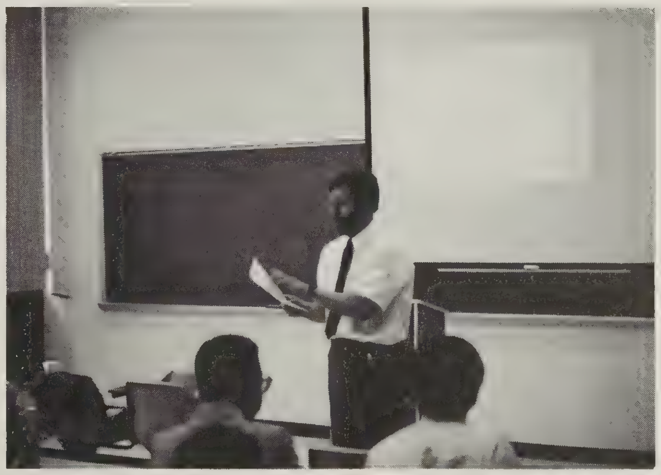
Bradley Thomas (left) and Marvin Oed (right) co-chaired the Continuing Education Coordinating Council's C.E. program on Diabetes held May 18th at the School of Pharmacy.



The Diabetes C.E. program featured small group sessions and exhibits such as this one from the American Diabetes Association.

The MPhA Scholarship Committee selected two second year Pharmacy Students to receive Scholarship assistance. Here President-Elect Lee Ahlstrom (left) presents a check to Mary Mease and Dana Washington receives her check from Chairman of the Board Maddy Feinberg (right).



The Diabetes C.E. program also featured a home-study portion which participants took before attending the Seminar. Tom Wiser explains a point to one of the small-group sessions during the program.

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Correction

The June, 1986 issue of this journal carried an article on calcium. In the Chart on page 22 the amount of elemental calcium in a can of Salmon was omitted by mistake. It should read 224 mg. of elemental calcium.

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calendar

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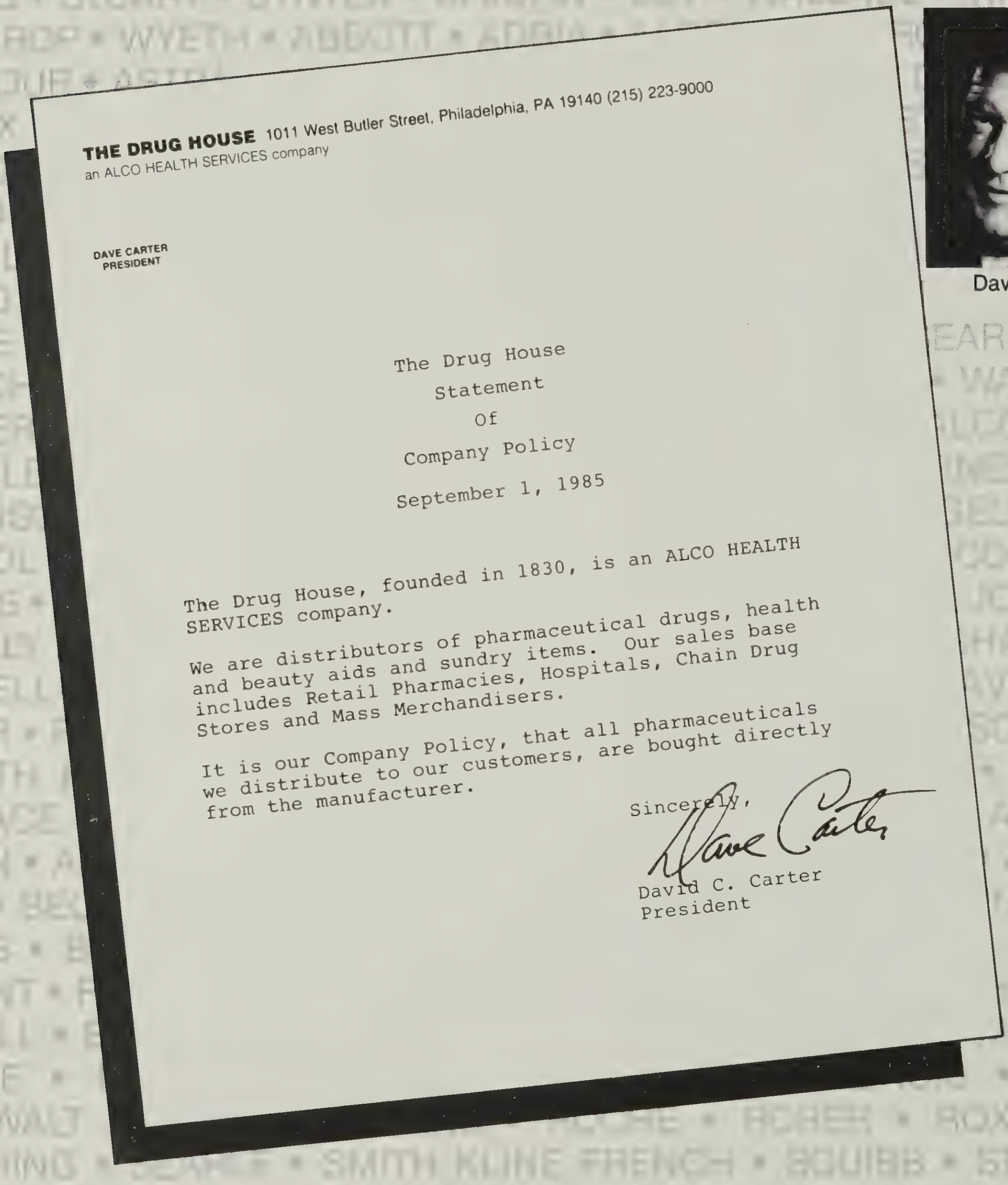

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DAVE CARTER
PRESIDENT

The Drug House
Statement
Of
Company Policy
September 1, 1985

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Sincerely,

Dave Carter

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THE
MARYLAND
PHARMACIST
Official Journal of
The Maryland
Pharmaceutical
Association

August, 1986
VOL. 62
NO. 8

104th Annual Convention
Pictures and Reports
Exhibits and Resolutions

Advising Consumers on Artificial Sweetners

— Thomas A. Gossel
— J. Richard Wuest

Speakers Bureau Outline: Nutrition, Vitamins and Minerals for the Older Adult

Timely Topics: Cancer, Nutrition, and the Elderly

THE MARYLAND PHARMACIST

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AUGUST, 1986 VOL. 62 NO. 8

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Delivered to the 104th Annual Convention

PRESIDENT'S REPORT

by
Madeline Feinberg

I join with my predecessors in thanking this Association for the Privilege and honor to serve as its president. Ron, you are right! The year flies by so quickly. But we've done a lot in a year, with the help and support from officers, committee charimen, Beverly (especially)!, Mary Ann, and most notably, the "rank and file" members. Many of these folks have taken time off from work and families, often at personal expense, to work for pharmacy through the Maryland Pharmaceutical Association.

Special thanks to David Banta. We all know what an outstanding job he does as executive director. But when you see it from the "inside" as only the president does, because, indeed, the executive director shares *all* information and decision-making with the president, then you begin to understand the extraordinary personal dedication which Dave brings to our Association and to the profession of pharmacy. He does a fantastic job for us!

We've had an exceptional honorary president this year. This Association in its wisdom, had chosen my department chairman, Dr. Peter Lamy, to serve as its honorary president, thus assuring that he would work for me this year. He sure did! Many of our accomplishments are directly attributed to Dr. Lamy's energies and expertise which he has most generously shared with us.

At The organizational level:

We established the Young Pharmacists' Caucus of the Maryland Pharmaceutical Association to provide a forum for recent graduates to identify common professional needs and to guide this Association in meeting these needs. Nearly 40 pharmacists now belong to this group. A newsletter, edited by Board member, Brad Thomas, has had three issues to date. The YPC group, it is hoped, will provide a source of future leadership for MPhA. This year, as a start, three Board members to be inducted at the Convention are members of the YPC.

We co-sponsored "Grassroots-21" at the invitation of Virginia Pharmaceutical Association President, Marianne Rollings. The all-day working conference was designed to give the grassroots practitioner an opportunity to consider what may be in store for our profession in the next 15 years, and to plan a proactive approach to possible future scenarios. There were 65 participants, from 8 states, including Hawaii. Proceedings from this conference will be published. It is hoped that this prototype meeting will be adopted by other organizations around the country. From the feedback we've heard, we think it will!

Our mid-year meeting in Annapolis attracted a record crowd, due in part to heavy turnout by the young pharmacists. For many it was their first MPhA meeting. In response to requests received at this meeting, the continuing education portion of the annual meeting will be devoted to current issues on nutrition.

Incoming President George Voxakis (left) and Treasurer Nick Lykos (right) present Madeline Feinberg with the Past President's Award at the Convention.

The Annual Convention in Ocean City is moving to a new place, the Sheraton-Fontainbleau Inn, an appropriate meeting to introduce some innovative convention programming. This year's meeting features presentations by three of the foremost medical nutritional scientists in the country. The selected topics should be of interest to other health care professional groups as well as to pharmacists, hence we have advertised this program to other organizations, thus increasing our association's visibility and offering providers the opportunity to participate with us at our annual meeting.

At the professional level

Pharmacist reimbursement for providing complicance packaging to medical assistance patients at risk to medication mismanagement was raised as an issue with Medicaid Chief, Doug Morgan at a Fall meeting. He recognized that there may be an opportunity to reduce drug-taking errors with the implication that consequences of these errors may be responsible for increased costs to the State. He has developed a position paper on the issue examining the scope of the problem (numbers of potential patients involved, cost of providing packaging, use of pharmacists to monitor regiments of high risk patients). Implementation of a pilot program is being discussed.

We participated with the Montgomery County Division of Elder Affairs and with the Department of Health, Services to the Aging, to discuss establishment of guidelines for drug administration in group homes for the elderly which are operated by non professional staff, and in adult day care centers where a registered nurse will administer medications. We continue to press for pharmacists monitoring component and have the interest of the Board of Pharmacy, the Division of Licensing and Certification and Medical Assistance in setting up guidelines.

"Location of the prescriber" is an issue that was raised two years ago by this Association when we passed a resolution seeking legislative mandate for hospital and other large institutions to put the clinic, ward or floor number as well as telephone number of location, in addition to legible signature of the provider, on the "generic prescription blanks" used in these institutions. At the suggestion of the Maryland Association of Chain Drug Stores, MPhA approached the Maryland Hospital Association to see if a voluntary program of compliance with this request would be feasible. The Board of Pharmacy is also concerned with this issue. In May, the M.H.A. met with the MPhA and a Board of Pharmacy representative and agreed with the

(Continued on page 8)

A Convention

Maryland Pharmacists gather
The 104th Annual Meeting

President Madeline Feinberg prepares to cut the ribbon opening the Exhibit Hall. Forty Exhibitors participated and a breakfast was provided.

MARYLAND
PHARMACEUTICAL
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The newly installed Officers and Trustees are shown following the Annual Banquet. (Top Row, left to right) President-Elect Lee Ahlstrom, Honorary President William Heller, Vice Speaker Brian Sanderoff, Vice President Elwin Alpern, Treasurer Nick Lykos, (Bottom row) Trustee Beverly Yachmetz, Trustee Stan Brown, Chairman of the Board Madeline Feinberg, President George Voxakis, Trustee Harry Hamet, Executive Director David Banta, and Speaker Gerry Epley. Not shown are Trustee Phil Fink and Trustee Martin Mintz.

Delegate Larry Young, (left) Chairman of the House Environmental Matters Committee which hears all health legislation, received the first annual Legislator of the Year Award from Executive Director David Banta at the Annual Banquet.

Bernard Lachman strolls in the Ocean City surf with wife Selma. Lachman is the outgoing President of the Maryland Board of Pharmacy and received the MPhA Distinguished Professional Achievement Award at the Annual Banquet.

REHABILITATION COMMITTEE

Three Commissioners of the Maryland Board of Pharmacy are shown in the Exhibit Hall. They are: (left to right) Paul Freiman, Leonard DeMino and Milton Moskowitz.

PHARMACEUTICAL
ASSO
Sheraton
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The President of the Ladies Auxiliary of the MPhA, Betty Alpern announced at the Banquet that LAMPA is changing its name to SAMPA and permitting male spouses of Pharmacists to join. Taking immediate advantage of this opportunity are Steve Yachmetz (right) and Michael Feinberg (right).

A special Banquet surprise was the presentation of a cake by Jerry Fine to Madeline Feinberg who was celebrating a wedding anniversary in conjunction with the Convention. Milton Moskowitz (right) served as Banquet Toastmaster.

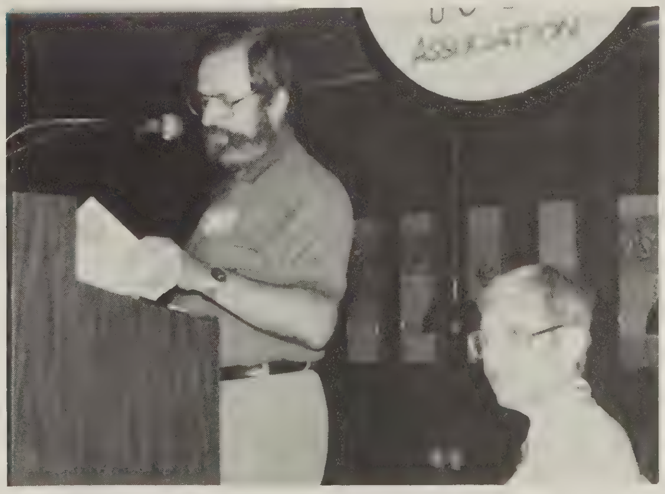
o Remember

n Ocean City, Maryland
une 22–26, 1986

Always a favorite, the annual crab feast in the Berlin, Maryland Firehall attracted 300 Pharmacists, family and friends.

Pictures courtesy of Abe Bloom,
F. A. Davis

Decked out in their best Hawiian Luau clothes, members enjoyed the first MPhA Luau at the Sheraton Hotel.



A "World Class" continuing education program on Nutrition and the Elderly was presented featuring discussions by Drs. Victor Herbert (at the Podium) and Daphne Roe (seated).

Convention Coverage

1986 Proposed Resolutions Submitted by THE RESOLUTIONS COMMITTEE

by Elwin Alpern, Chairman

Resolution No. 1 (passed)

WHEREAS, out-of-state mail order prescription drug programs do not provide patient counseling or immediate service and are unregulated by the Maryland Board of Pharmacy, and

WHEREAS, these programs deny the patient's right to freedom of choice for the source of prescription drugs based on price and professional service, and

WHEREAS, these programs eliminate the pharmacist's role in drug monitoring for the patient's entire drug therapy, and

WHEREAS, these programs may contribute to the serious problem of drug abuse in our society and drug diversion within the health care delivery system,

THEREFORE BE IT RESOLVED, that the Maryland Pharmacists Association continue in its effort to obtain regulation for the protection of the public health for out-of-state mail order prescription drug programs, and

BE IT RESOLVED, that the Maryland Pharmacists Association continue its efforts to educate the public on the disadvantages of mail order prescription drug programs and the benefits of contemporary community pharmacy practice.

Resolution No. 2 (passed)

WHEREAS, continuing education for pharmacist relicensure in Maryland will soon be required, and

WHEREAS, many of the major drug manufacturers are approved by the American Council on Pharmaceutical Education as providers of continuing education, and

WHEREAS, these companies can draw upon major resources to provide continuing education to Maryland Pharmacists,

THEREFORE BE IT RESOLVED, that the Maryland Pharmacists Association seek a method for publishing a compilation of these continuing education opportunities available from the major manufacturers for the use and benefit of Maryland Pharmacists.

Resolution No. 3 (passed)

WHEREAS, Pharmacists are an integral link in the delivery of drug therapy to the patient and is often the source used by the patient when seeking information about drug therapy, and

WHEREAS, Pharmacists are the most accessible, best distributed and most trusted member of the health care team, and

WHEREAS, Pharmaceutical manufacturers have a responsibility for the health and safety of the patients who consume their products through the prompt provision of information related to that product,

THEREFORE BE IT RESOLVED, that the Maryland Pharmacists Association request that pharmaceutical manufacturers inform pharmacists as well as physicians on emergency matters such as recalls and changes in prescribing and/or labeling of their products, and

BE IT RESOLVED, that the Maryland Pharmacists Association also request that Pharmaceutical manufacturers promptly provide pharmacists with drug information on any new products which are released.

Incoming President George Voxakis (left) accepts the gavel of office and the traditional captain's hat following the installation ceremony by Past President Ronald Sanford (right).

Resolution No. 4 (tabled)

WHEREAS, the University of Maryland School of Pharmacy has primary responsibility to educate Pharmacists for the State of Maryland, and

WHEREAS, the State of Maryland and surrounding areas appear to be experiencing a pharmacy manpower shortage,

THEREFORE BE IT RESOLVED, that the Maryland Pharmacists Association requests that the University of Maryland School of Pharmacy conduct a study to determine the effects of changing to an all-Pharm.D. curriculum upon the Pharmacy manpower supply.

Resolution No. 5 (passed)

WHEREAS, the pharmacist is the most accessible, best distributed and most trusted member of the health care team, and

WHEREAS, the Maryland Pharmacists Association has previously coordinated programs on health education for the general public,

THEREFORE BE IT RESOLVED, that the Maryland Pharmacists Association actively support Medication Awareness Month (October, 1986) with programs and printed information for the general public.

Resolution No. 6 (passed)

WHEREAS, Commercial nonprofit institutions, including hospitals, and health maintenance organizations, are obtaining drugs at discriminatory prices and reselling them in competition with for profit pharmacies, and

WHEREAS, such discriminatory sales and resales by commercial nonprofits was never contemplated by Congress in passing an exception from the Robinson-Patman Act for charitable institutions in 1938, and

WHEREAS, such commercial nonprofit institutions are receiving tax and other economic benefits which subsidize their competition with for profit pharmacies,

THEREFORE BE IT RESOLVED, that the Maryland Pharmacists Association seek and support the restatement or modification of the Nonprofit Institutions Act exemption from the Robinson-Patman Act and such other legislative changes as are necessary to restore fair competition.

Resolutions submitted under New Business

Resolution No. 7 (amended and passed)
Submitted by Lee Ahlstrom

WHEREAS, many pharmaceutical manufacturers sell drugs to foreign countries and institutions in the United States at a fraction of the price charged to wholesalers and pharmacies, and

WHEREAS, American consumers are being forced to pay higher prices for prescriptions in pharmacies and even high prescription drug prices by hospitals, and

WHEREAS, these discriminatory pricing practices lead to drug diversion and adverse consequences to the health and welfare of consumers due to drugs that are improperly stored, mislabeled, expired or adulterated.

THEREFORE, BE IT RESOLVED, that the Maryland Pharmacists Association support the concept that pharmaceutical manufacturers charge a single uniform price to all purchasers of pharmaceuticals under the same conditions.

Resolution No. 8 (passed)
Submitted by Lee Ahlstrom

WHEREAS, in many cases drug samples are dispensed without adequate dosing instructions for the patient, and

WHEREAS, many times drug samples are dispensed in quantities that far exceed their intended purpose as starter doses, and

WHEREAS, drug samples have been found to be one of the major sources for drug diversion and its adverse consequences to the health and welfare of consumers,

THEREFORE, BE IT RESOLVED, that the Maryland Pharmacists Association support the elimination of all drug sampling and replace it with a coupon issued by the manufacturer for a starter dose that would be dispensed by the pharmacist in the same manner as any physician's prescription, and

BE IT RESOLVED, that the manufacturer offering the coupon would reimburse the pharmacist for the product dispensed, plus the pharmacist's dispensing fee.

Resolution No. 9 (passed)
Submitted by Madeline Feinberg

WHEREAS, abuse of prescription drugs represents an important and growing health care concern in our society, and

WHEREAS, it is the ultimate mission of any price advertising to attempt to increase sales of a product and therefore increase public consumption, and

WHEREAS, Controlled Dangerous Substances, as defined by Article 27 of the Annotated Code of the State of Maryland, are those prescription drugs which represent the greatest potential for such abuse,

THEREFORE, BE IT RESOLVED, that the Maryland Pharmacists Association seek methods to end prescription price advertising of all Controlled Dangerous Substances as inappropriate and contrary to the good of the public health.

Donna Eby, representing the Student APhA Chapter at the School of Pharmacy, delivers their report to the House of Delegates.

STUDENT AMERICAN PHARMACEUTICAL ASSOCIATION REPORT

by

Donna Eby, Chairman

The Maryland Chapter of the Student American Pharmaceutical Association has had a very busy and successful year. Student participation was at its highest level in several years and many projects were completed. This enthusiasm and our fund raising efforts has started us off on good footing for next semester.

Our fund raising campaign has included a raffle and a salad bar. We also wish to thank the Alumni Association and the Maryland Pharmaceutical Association for their generous donations. Much of these funds were used to assist students attending the APhA Annual meeting in San Francisco. Ten students attended the convention and enjoyed not only the scenery but the educational programs and the interactions and many contacts made with students and pharmacists from across the country. The MPhA mid-year meeting in Annapolis was also well attended by our members as was the NARD Home Health Care meeting in Baltimore. Maryland students helped man the MPhA booth at the NARD exhibitions.

We are proud to announce the re-issuing of our school newspaper the Pharmakon. Two issues have been published since March. The paper has excellent editors and staff and was well received by the students, faculty, and administration. Four issues are planned for the next school year. If the MPhA or any of its members wish to submit articles please contact the staff through Dave Banta.

Our Speakers bureau was also very active this year. Lectures were given on Pharmacy Residencies, the new NAPLEX exam, and the Cumberland AHEC program. Many other speakers are planned for next semester, as well as some panel discussion on student concerns.

Our semi-annual Coffeehouse was held in May and was once again a huge success. Our lampoon newspaper the UTC was published 6 times this past year and proved that even with the students course load there was still some humor left in them.

SAPhA has enjoyed a helpful relationship with the faculty and staff at the school and the staff at the MPhA and we look forward to this continuing next semester.

Convention Coverage

(Continued from page 3)

need to change current practice. They assured us of their willingness to cooperate and will implement a program to change the way prescription blanks are written. They agree that, after one year, if non-complying institutions cannot be encouraged to meet the guidelines, they will work together with MPhA, and the Board to consider joint legislative action. This, we all agree, is a last resort.

At the political level:

We have become politicized! The association hired a lobbyist this year, for the first time, and in the nick of time! Competition for prescription business from groups other than pharmacists (I include mail order in this category), has forced this Association to play the political game just like the other "Big Boys". We too, need to put bills into the legislature to protect both our professional role and the public interest. Our dollars paid off this year with passage of SB 830. Next year we need to look at mail order operations. Shouldn't they too meet the same standards as pharmacies located in states where citizens receive medications?

MPhA formal recognition of legislators who supported our issues is being given for the first time this year. Delegate Larry Young, Chairman of the House Environment Matters Committee, and Dennis Rasmussen, former chairmen of the Senate Finance Committee and candidate for Baltimore County chief executive, will receive formal recognition at this Association's Annual Banquet. We must never forget our friends!

Finally, with regard to political realities. Remember, at some point in time, every representative in Annapolis, every member of Congress, will need to have a prescription filled and will go to his local pharmacy. It may be yours. Their impression of pharmacy is what they will remember when issues come up touching on pharmacy practice. At this hearing for SB 830, the Senators said Hello, across the room, to their pharmacists, Tony Padussis and Nat Futeral. The delegates publically said Hello to Nick Lykos and Les Feldman. The Mayor always says Hello to Mark Levy, and the Mayor is now running for Governor. Your representatives should know who you are. Be sure they remember that you support them.

There was much more that happened this year. This association was involved in programming for the APhA Annual Meeting and the NARD Home Health Care Conference held in Baltimore. We got approval for DUR which will not only be an opportunity to exercise professional knowledge to serve the state, but will give us access to information regarding drug use in our state which will help us to design quality services for our patients. We are also buying a new computer, MSHP is moving into the Kelly Building and we continue to work closely with this group. We spent a little money this year, but I'll let Nick tell you all about that.

In conclusion, Ron, I must ask: Did it hurt too bad having a woman president of the Association?

I won't be able to go back to "doing windows" because I hope that George will ask me to stick around and help him out now and then. Indeed. I even have a job for George. Let's form a "Political Hot Line" for next year. Based on our experience during the last session of the legislature, we need to organize a statewide communications network so we can get the word out in a matter of hours. In conjunction with this network, we need to publish a political map of our state so pharmacists can see who their representatives are and learn how to reach them when they need to.

MUP
ASSOCIATION

President Madeline Feinberg (left) presents the Honorary President's Award to William Heller (right) at the Annual Banquet. Heller is the Executive Director of the United States Pharmacopeial Convention.

On behalf of the officers of this Association and its members, let us wish George Voxakis a successful and fulfilling year as President of the Maryland Pharmaceutical Association.

Thank you.

EXECUTIVE DIRECTOR'S REPORT

by

David A. Banta, C.A.E.

It has been a most productive year for the Maryland Pharmacists Association. A great deal of credit must go to President Madeline Feinberg. More than any other President I can remember, Maddy participated in almost every major activity of the Association over this past year. Her unbounded energy and enthusiasm are truly contagious. She seemed to be everywhere and was willing to go anywhere for the Association. I think she probably has set the one year record for meeting attendance. It was a pleasure to serve with her.

Here are a few of the past year's highlights which have not been mentioned in other reports to this House. Following up on the trend toward a closer working relationship with the Maryland Society of Hospital Pharmacists, we held a joint Board meeting with MSHP in August to discuss the possibility of holding a joint convention, cooperation with the Rehabilitation Committee, work on legislation and other areas of cooperative activity. MPhA also worked closely with the Virginia Pharmacists Association to produce the very successful "Grassroots 21" future planning seminar. Maddy was instrumental in bringing this about and you will be hearing more about the results of this conference. The Association endorsed a Coupon Redemption program through the Mid Atlantic Food Dealers Association. It has been a successful program with over 60 pharmacies participating. The Association also endorsed a new payroll deduction investment plan which is now available to the membership. This Association joined a coalition of other concerned health care provider associations and organizations called the "Healthy Majority" to promote limitations on smoking.

Our two membership meetings were unprecedented successes. The Mid year meeting in Annapolis drew a record crowd and the programming received rave reviews. The 1985 annual convention was the largest we have ever had resulting in a successful exhibit program and a record profit for the Association.

Early last year, President Feinberg announced as one of the goals of her administration, the formation of the Young Pharmacists Caucus. I am very pleased that the initial introductory dinner, newsletters and participation that has resulted shows a new commitment to the Association on the part of our young (and young at heart) Pharmacists. Members of the Association participated in the White House Conference on Small Business. On behalf of MPhA, Sam Lichter delivered testimony to a Congressional Committee investigating the Liability insurance crisis. I was asked by APhA to serve on a National Task Force to study the issue of sampling. The MPhA hosted the annual Dixie Sunrise Breakfast as part of the NARD annual Convention. The Alumni Association has expressed interest in seeking assistance from the MPhA in maintaining its mailing lists. The MPhA was very visible on the program for the NARD's Home Health Care Conference held here in Baltimore.

Perhaps the most significant changes for the membership was the decision of the Association, at the urging of BMPA, to raise funds to hire a professional legislative representative, Mr. Judson Garrett, for the 1986 session of the Maryland General Assembly. This has resulted in the unprecedented successes reported to you by the Legislative Committee. Politically, we have entered a new era. In addition to that, I am pleased to report that the long-awaited Drug Utilization Review contract with Medicaid will soon be funded. This will allow us to hire additional professional and secretarial staff and to purchase a more powerful computer to increase the efficiency and our ability to handle the numerous records we have acquired for various organizations in recent years.

I was pleased to serve over the past year as Chariman of the Board and Chairman of the Nominating Committee for the Maryland Society of Association Executives. I also served as Chairman of the Nominating Committees for the State Pharmaceutical Editorial Association and the National Council of State Pharmaceutical Association Executives.

We have had numerous contacts with various HMO's concerning the issue of freedom of choice. We have continued the public education campaign concerning the disadvantages of mail order prescription drug services. We have had discussions with Blue Cross and Blue Shield and the Johns Hopkins Health Plan concerning the formation of a Pharmacy PPO. Over the past year, a subcommittee of the Board of Trustees has studied the possibility of forming an Association sponsored buying cooperative for Maryland Pharmacists. Following presentations before this House at this Convention, we anticipate a final decision on this matter. We have also had frank discussion with Union Trust Bank concerning their endorsement of a mail order prescription drug plan. They now have indicated a willingness to cooperate with the MPhA to promote community pharmacy services.

This Association produced a record number of attendees for the APhA Convention in San Francisco. President Feinberg was appointed Chairman of the Section on Home Health Care. Once again, Maryland was very visible at the national convention. We are also participating in the formation of a Pharmacy special interest group within the American Gerontological Society.

At last year's House of Delegates meeting a resolution was passed which stated in part: "Therefore, be it resolved that the Maryland Pharmaceutical Association submit an oral and written report to the membership at the following annual meeting that states what steps the Association has taken to satisfy the intent of each of the resolutions. . . ." It is my intention to discuss the disposition of the resolutions passed at last year's House of Delegates meeting in this report. Thus the intent of the above resolution is explained and, hopefully, satisfied.

Another resolution which was adopted called for the regulation of dispensing physicians. This, of course, led the Legislative Committee to commit to the successful passage of SB 830 which is reported at length in the Legislative Committee Report.

Prince George/Montgomery counties were well represented at the Convention again this year. Area Pharmacists are shown at the reception before the Annual Banquet.

A third resolution called for a statewide educational symposium of administrators of health care plans to discuss patient freedom of choice. The Board of Trustees discussed this resolution and concluded that it should be handled on a small group basis and this led to many of the meetings I reported earlier.

A final resolution, passed last year under new business, which called for the Association to begin the process of changing its name to "The Maryland Pharmacists Association." The Board again discussed this matter and referred it to the Constitution and Bylaws Committee for necessary action. I would anticipate that, as office supplies are depleted and stationary is reprinted, the name change will be gradually accomplished in the next several months.

The policy making mechanism of this Association is responsive to the wishes of membership as expressed by this House of Delegates. The Board, Officers, Trustees and Committee Chairmen take into account the resolutions adopted by this House as they act on your behalf and I am pleased to give you this feedback.

Finally, I wish to thank our office staff. Many of you know the hard work that Beverly and Mary Ann perform for Maryland Pharmacists. We are all fortunate to benefit from their skills and dedication and they both have my personal gratitude. Next time you call the office say congratulations to Beverly who has been with the Association for five years and Mary Ann who is completing twenty-five years of service as our Comptroller/bookkeeper.

Once again, it has been my personal pleasure to serve as your Executive Director for the past year. I hope to stand before you next year with an equally extensive report on our accomplishments. This is a great Association of Pharmacists with many hard working volunteers. To each of you, I offer my sincere thanks for all of your efforts over the past year. You have made my job easier and personally rewarding. I wish to thank all of the members of the Board of Trustees and the Officers for their contributions during this past year. We had a lot of fun and worked hard too. With all of you, I look forward to the future with confidence and optimism.

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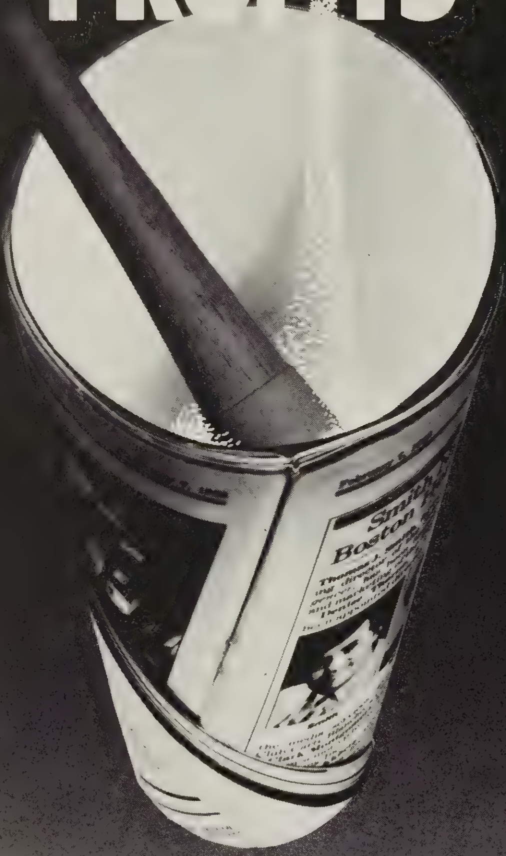

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NEWSLETTER COMMITTEE REPORT

by

Melvin Rubin, Chairman

I have had the pleasure of being associated with the Newsletter in its present format since 1974 when then President Paul Freiman pulled rank and forced me to discontinue the Baltimore Bulletin in favor of the Maryland Newsletter. Next year when he retires from the Board of Pharmacy I may have a special present for him.

This year the publication was less regular than usual but timed to help with special projects such as the Blue Cross Mail Order Crisis, and fund raising for legislative efforts.

Two things will help make the newsletter better—a better flow of information into the office particularly of events being held by MPhA local affiliates and other pharmacy associations, and information concerning awards, accomplishments, happenings of members of the Association. Nothing sells a newspaper better than peoples names being mentioned other than fresh news. Since our staff included one part time reporter, we could use all the volunteer help we can get.

While you are at it, why not suggest features you would like to see regularly and tell us if you do or do not like those that we use (i.e. FDA recalls of note).

Thanks to Beverly for her work in typing and formatting with a computer that leaves a bit to be desired. And especially thanks to Dave Banta who does the last minute touch up. He always has time to do what I can't seem to handle.

PUBLIC AFFAIRS COMMITTEE REPORT

by

Phillip P. Weiner, Chairman

The Public Affairs Committee met frequently during the year but did not accomplish as much as it would have liked to. We did do several talk shows on the radio and a couple of spontaneous spots on daily news portions of the radio programs.

I hope to add a dozen or so new interview programs to "Your Best Neighbor" series in the coming year. This should upgrade the program's interest quotient.

EMPLOYEE/EMPLOYER RELATION COMMITTEE

by

Dudley Demarest, Chairman

The Employee/Employer Relations Committee was reactivated this year and called its first meeting since October 1982. The committee discussed at length many issues at its first meeting. They included:

- Management training and career development
- Salary and fringe benefit survey
- Recruitment for pharmacy school
- Greater sensitivity and negotiation in the employment setting
- More participation in association sponsored meetings
- Information on part and full time employment positions
- Dealing with stresses that are unique to pharmacy practices
- Problem solving seminar
- Employee pharmacists "Survival Kit" for new graduates
- Methods for employee recruitment by independent owners
- Pharmacy "Policy and Procedures" Manual

Peter Lamy (left), Director of the Center for the Education of the Elderly and the Elder-Health Program at the School of Pharmacy, receives a check from Walter Weglein representing the Parke Davis Company for $50,000 in continued support of the program. Lamy is the out-going MPhA Honorary President.

Of these areas several were selected as projects for the current committee.

The Employee/Employer model employment agreement was again published in the Maryland Pharmacists, as was an announcement of the Part Time Employment clearing house operated through the Association. The Salary and Fringe Benefit Survey was mailed to Maryland Pharmacists this spring. Replies to the survey are still coming in and we hoped to publish the results in the Maryland Pharmacist by July.

Several projects are now in progress. A continuing education weekend is being planned. The program will be called a "C.E and Ski" weekend and is planned for February 1987 at a local ski resort. The program will include seminars on stress management. The total cost of the package, which includes meals, lift tickets, lodging and a reception should be less than $100.00.

A model Pharmacy Policy and Procedures Manuel is being developed by several committee members as well as a Survival kit which will include information on employment, finance, stress management, time management, advanced education opportunities, and membership benefits offered by Association among other things.

The committee is actively searching for more members, both employer and employee. We have many worth while projects that have been placed on a back burner because of our lack of manpower.

TRAVEL AND CONVENTION REPORT

by

Elwin Alpern, Chairman

Due to worldwide terrorism our travel plans since the last convention had to be modified. We refunded in full to all members their money for the Greece trip, scheduled October 1985. We hastily put together a London Trip to salvage the money lost to the Greek tour operator. I wish to emphasize the Association did not lose any money.

In January 1987 Continuing Education is due to be started. To help our members we will make every effort to include an accredited C.E. program on our trips. Our next trip is planned January 14, 1986 to Hawaii. Our Executive Director David Banta, will put together an approved C.E. program.

Our 1985 convention at the Carousel in Ocean City had an attendance of 300 people. There were 33 exhibitors in 1985 with fees of $9,700. and contributions of $3,475. Registration fee accounted for $11,399. The net profit was $12,330.00. We decided to move to the Sheraton as Ocean City conventions are well attended and the Sheraton is on the upgrade and the Carousel is on the down grade.

In February 1986 a trip to Puerto Vallarto, Mexico was attended by 38 people. Although it was not a smashing financial success all those that attended had a fantastic vacation.

I want to thank David Banta and Mayer Handelman for their help during the last year. A special thanks to Beverly and Mary Ann.

Thank you.

Elwin Alpern, Chairman of the Convention and Trips Committee, has a lot to smile about during the successful 1986 Convention. He also served as Vice Speaker of the House of Delegates and Chaired the Resolutions Committee.

LEGISLATIVE COMMITTEE REPORT

by

Paul Miller, Chairman

The 1986 Legislative Committee has been extremely busy and some dramatic changes have taken place. The MPhA was fortunate to retain the services of Mr. Judson Garrett as a professional lobbyist to assist us in our legislative efforts in Annapolis.

The main issues that we addressed this year were:

1. Regulation of dispensing physicians
2. Regulation of mail order prescriptions
3. Immunity for the rehabilitation committee

We wish to thank those pharmacists who have supported us by donating time, effort and contributions which enabled us to achieve some of our goals. There is still much work to be done. In order to retain our lobbyist and accomplish future goals, we will need the support of every MPhA member. We also want to thank David Banta for his guidance and help.

The following bills of interest this year were:

SB 830 was the bill to discourage Physician Dispensing. Included with this report is a complete description of the activity related to this bill and the votes in Committee and on the floor of both Houses of the Maryland General Assembly. This is the first time that we have published the results of the votes on a pharmacy bill. We hope that the feedback to the legislators from pharmacists who are politically involved will send a message about our increased political awareness. This bill was signed into law by the Governor.

SB 831 was the bill to grant immunity from prosecution to the Pharmacist Rehabilitation Committee. You may want to read the report of that Committee at this Convention to see how important this bill is to the important work being accomplished for all Maryland Pharmacists. The bill was signed into law by the Governor.

HB 1465 was our bill to regulate out of state mail order prescription drug firms. Since it is illegal for the Board of Pharmacy to unduly burden competitors, even out-of-state competitors, the bill had already received approval for its constitutionality before it was introduced. It would have required that firms sending prescriptions into Maryland have a copy of the Maryland Pharmacy law book, a copy of the Maryland State Formulary and maintain a toll-free telephone line for the use of patients. It also would have required that Prescriptions for Maryland patients be readily identifiable and readily retrievable for inspection in the event that there would be a consumer complaint or problem. Unfortunately, there was a great deal of mis-information spread about the effect of this bill. Many elderly consumers were told their prices would increase. The bill went down to defeat when the Committee decided that SB 830 had a higher priority and it was impossible to pass both bills with the level of resources available to the Association.

The Medical Society succeeded in passing liability tort reform measures which also benefit Pharmacists. These include a cap on court awards for pain and suffering and a strict definition of an expert witness. While Pharmacy does not have as large a problem as Medicine does with its liability insurance, the long term effect of this reform legislation could be significant.

HB 659 was an important bill that has not received a lot of publicity. It requires that the third parties pay providers within thirty days on undisputed claims or be responsible for the payment of interest at one and one-half percent. The bill passed and was signed by the Governor. The Association will be monitoring the effect of the bill and is prepared to bring its existence to delinquent third party payors.

A package of bills designed to address the problem of drug abuse in this State was introduced and passed. Among other things, these bills prohibit pre-printed prescription blanks, permit no more than two prescriptions per blank and prohibits the use of a signature stamp by the prescriber.

As most of us know by now, the Attorney General has issued an opinion that clears the way for Nurse Practitioners to prescribe drugs within the limitations of the agreement with their supervising physicians. For many years, this practice had been held up by a technicality in the Pharmacy law which had not included Nurse Practitioners under the definition of "Authorized Prescribers." We are certain that this issue will be re-examined in the next session of the legislature.

See the June issue of the *Maryland Pharmacist* for the actual text of many of these important bills. Help the work of the Committee by supporting the Lobbying Fund and PharmPAC. Get to know your local legislators and participate when called upon by joining the telephone contact system which will soon be established, volunteering to testify, or serving on the Legislative Committee itself. In these days of clear challenge and risk to our profession, we must all make a commitment to help. Thank you.

MEDICAID COMMITTEE REPORT

by

Mark Levi, Chairman

As a first year committee chairman, this has been a learning experience. The state through monthly meetings has advised us that the IDC program of interchangeable drugs has saved the state an estimated 1.2 million dollars. With this in mind we were not given an increase in the original budget but have an oral promise that there will be an increase in the supplemental budget. We look forward to this promise with hope that the increase will be up to 50 cents. The next experience was with the highly utilized drug list. Although a 4 page list was proposed, we were able to convince the state that many of the larger sizes and direct pay drugs were a burden to independent pharmacies. In the same vein the IDC list was pared down because of an increase in the minimum amount of prescriptions presented to the state for inclusion on the IDC list. President Feinberg recently presented a case of special packaging to the state and has been received favorably. This may lead to better control for medication of elderly and mentally patients.

I feel certain that there will be an increase in the professional fee as long as we maintain a high profile and become politically active. It is inevitable that these two items go hand in hand as well as other items that are of interest to pharmacists of the state of Maryland.

INDUSTRY RELATIONS COMMITTEE REPORT

by

Mark Golibart, Chairman

The Industry Relations Committee of the Maryland Pharmaceutical Association met to discuss a number of important issues.

The Committee discussed major legislative issues in the last session of the General Assembly including a proposal to place needles and syringes on prescription in Maryland, and mandating the location of the prescriber on the prescription.

Discussions were held on the Congressional hearings investigating drug diversion and the misuse of sampling. Policy on these issues seem to vary greatly from company to company.

The Committee continued to be concerned with prescription drug price increases, freedom of choice of pharmacy providers in HMO plans and Mail order prescription drug plans.

The Committee has also been following the on-going negotiations between the Association and the Medicaid Program regarding the Generic Drug Price Regulations and the Drug Utilization Review Proposal (DUR).

The Committee continued its on-going ombudsman activity with regard to return goods policies. On behalf of the Committee, staff made several inquiries throughout the year to help pharmacists establish constructive dialogue and productive results from manufacturers on this issue.

The Committee continues to be open to suggestions from the membership and openly solicits, at this time, your suggestions concerning issues involving Pharmacy —Industry relations. I appreciate the work of the Committee members and the special contributions of the office staff to the work of the Committee.

President Madeline Feinberg presents Lee Ahlstrom with the outgoing Speaker of the House Award.

SPEAKER OF THE HOUSE REPORT

by

Lee Ahlstrom, Speaker of the House

It has been a distinct pleasure to serve as Speaker of the House this past year. I would like to take this opportunity to thank the officers, board members, staff of the Maryland Pharmaceutical Association, especially Executive Director David Banta for their help and support at the mid-year meeting and also at the convention at Ocean City.

The mid-year meeting was held February 2, 1986 at the Annapolis Hilton. A capacity crowd of 130 participated in the program which featured a review of newly marketed drug products by Thomas Gossell and J. Richard Wuest, and also an extensive review and discussion on "What's Right with Pharmacy." The Pharmacist's growing influence in the expanding OTC market by Jack Robbins. Grady Dale, Assistant Dean at the University of Maryland School of Pharmacy, honored the sponsors and participants of the scholarship program sponsored by the University of Maryland School of Pharmacy. A short House of Delegates meeting followed in the Executive Director David Banta briefed the House on legislation before the General Assembly at Annapolis. The nominating Committee reported on the nominees for Officers and Trustees of the Association and also the Board of Pharmacy nominees.

In closing, I would like to thank all the members who participated in the various activities of the association in this past year, it was largely through their efforts that we were successful in the legislature, however there remains much work to be done and this will require your continued support. In the coming year we will see the implementation of the DUR program which will give us greater visibility with the state and also the medical community, this along with other programs that will come on line will provide a stronger fiscal base from which we can work toward the common goals of the association and its membership.

More Convention Reports will appear in the September issue of the *Maryland Pharmacist*.

This summer, we got a glimpse into the future.

These four outstanding students joined us for the summer of 1986 at The Upjohn Company. By summer's end, we taught them about our industry—everything from manufacturing to marketing and sales. They taught us that integrity and freshness of vision are still very much alive in pharmacy.

Every year, we invite four students to join us for our 10-week National Pharmaceutical Council-Student American Pharmaceutical Association (NPC-Student APhA) Internship Program. We've hosted 54 of these students since 1973. But this year had a special meaning: it's our 100th anniversary. During the year, we've looked back on our history, and forward to plans for future advancements. Our interns this summer gave us the renewed assurance that the future of pharmacy is in good hands. We'd like to thank them for that.

From left to right:

Michael L. Manolakis—University of Southern California School of Pharmacy
Kecia R. Cooper—Ferris State College School of Pharmacy
Kathy L. Coburn—University of Michigan College of Pharmacy
Thomas P. La Martina—University of Maryland School of Pharmacy

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STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 7

Advising Consumers on Artificial Sweeteners

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. present the background and important considerations of the discovery of each artificial sweetener;
2. relate artificial sweeteners to sucrose in response to nutritive value;
3. give ideas concerning an eventual remarketing of cyclamate in the U.S.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Objectives

At the conclusion of this lesson, the successful participant should be able to:

1. discuss the nutritive value of each artificial sweetener;
2. relate current information concerning toxicological issues of each artificial sweetener;
3. explain the limitation of procedures used for testing artificial sweeteners for safety;
4. list sugars other than sucrose which are used to sweeten food and drug items;
5. discuss important consumer information needed for correct use of each of the artificial sweeteners.

Artificial sweeteners have been the topic of scientific debate and consumer concern for the past several decades. Scientists and the public are concerned about the safety of the sweeteners; and the scientific community also questions the reliability and appropriateness of the laboratory methodology used to assess the safety of these products.

This month's lesson discusses the history and characteristics of artificial sweeteners, and suggests what the future may hold for each of them. It explains the scientific rationale for the current concerns. And it also offers consumer information on artificial sweeteners in general and discusses aspartame, a recently introduced sweetener, in more detail.

Satisfying America's Sweet Tooth

Humans have sought ways to sweeten their food since earliest times. A cave painting in southern Spain shows an inhabitant stealing honey from a nest of wild bees. References to sugar and honey are common from Biblical times.

Today, Americans continue to love their sweets! Sugar consumption represents an average 16 to 17 percent of Americans' total calories. This amounts to 1.5 gm/kg or 100 to 150 gm/day. Sixty-five percent of this sugar is ingested in processed foods and beverages; the remainder is added at home.

Excess sugar (sucrose) has been medically linked to development of dental caries (cavities), obesity, and hypertriglyceridemia. While sugar does not cause diabetes, it can exacerbate symptoms and interfere with control of the disease. Artificial sweeteners permit Americans to continue to satisfy their craving for sweets while curtailing development of the aforementioned conditions.

The artificial sweeteners differ from one another in chemical composition. Each of them also has advantages and disadvantages. The properties of an ideal artificial sweetener are listed in Table 1.

TABLE 1

Properties of an Ideal Artificial Sweetener

The ideal artificial sweetener should be:
Sweeter than sucrose
Colorless
Odorless
Noncarcinogenic
Good tasting
Stable to heat
Soluble in water
Inexpensive
Nontoxic
Metabolized to nontoxic compounds, or excreted unchanged

Ref: O'Brien L, Gelardi RC: *Chemtech* 11:274, 1981

Saccharin

Saccharin, which was discovered in 1878, was originally employed as an antiseptic and food preservative. It did not gain public acceptance as an artificial sweetener until 1907. It has been the most widely used of all the artificial sweeteners except during the 1950's and 1960's when cyclamates dominated the market. In 1978 Americans consumed six million pounds of saccharin, mostly in soft drinks.

Saccharin sodium is approximately 300 times sweeter than sucrose and contains no calories. It is freely soluble in water (1 gm dissolves in 1.2 ml water), stable at temperatures up to 150°C (302°F), and has an acidic pH of 3.3. Saccharin is not metabolized and is excreted unchanged. Some individuals who use saccharin report a bitter aftertaste.

Canada's Health Protection Branch (similar to the American Food and Drug Administration) first questioned saccharin's safety in 1974. Rats were given massive daily doses of 2,500 mg/kg. As a result, 21 of 200 animals developed bladder tumors, versus only one positive response in 100 control animals.

The study was completed in 1977. FDA responded to it stating, "The findings indicate unequivocally that saccharin causes bladder cancer in animals."

In 1980 a study cosponsored by FDA and the National Cancer Institute investigated the potential problem in human epidemiologic studies. Nearly 9000 saccharin users were found to not be at any greater risk for developing tumors than the general population.

But not all study results were as favorable. The investigation showed that persons who smoked heavily and those who used excessive saccharin (two or more diet colas or six or more packets of artificial sweetener per day) were at greater risk of disease. Women who ingested diet beverages or sugar substitutes at least twice daily were at 60 percent greater risk of developing bladder cancer than women who did not use saccharin.

Impelled by the Delaney Amendment of the Pure Food, Drug and Cosmetic Act (which requires removal from the American market of food additives that cause cancer in animals), Congress quickly enacted a moratorium on the ban. This was largely due to public outcry that persons (e.g., diabetics) needing an artificial sweetener would be left without one. More than 100,000 public comments against the ban were documented.

So that the public would be warned of potential toxicity from using the product, labeling statements were required on each food item that contained saccharin. Another warning was to be posted in each establishment that sold food items containing saccharin.

Canada banned all commercial uses of saccharin, but permitted it to be sold in pharmacies only. It had to bear a warning of its cancer-causing potential.

The Joint Food and Agricultural Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives recommends a maximum of 2.5 mg/kg/day of potassium or sodium saccharin as a safe intake. It is approved for use in over 80 countries.

Cyclamate

Cyclamate was approved for commercial food use in 1951. The sodium and potassium salts were later marketed for use as a tabletop sweetener under the trade name Sucaryl®.

Cyclamate was reported to be 30 times sweeter than sucrose, less sweet than saccharin, and noncaloric. Sucaryl® was a mixture containing 10 parts cyclamate and 1 part saccharin. The saccharin provided sweetness while the cyclamate masked the bitter aftertaste.

The product was, therefore, widely used in canned foods, chewing gum and mouthwashes, and quickly became the leading artificial sweetener in America. It dominated the market throughout the 1950's and 1960's; Americans were reportedly consuming 18 million pounds annually in the late 1960's.

Cyclamate had been thoroughly evaluated for toxicity problems prior to its marketing approval and FDA pronounced it safe for use. When levels of approximately 5 gm/day (equivalent to about three quarts of diet soda) are consumed, a laxative adverse effect is possible.

Toxicity studies continued following marketing. While originally reported to be excreted unchanged, subsequent work showed that up to one-third of all humans metabolized it to cyclohexylamine. Cyclohexylamine was a known toxicant capable of causing dermatitis, convulsions and chromosomal damage in animals.

Continued investigation eventually revealed that 12 of 80 rats fed cyclamate and saccharin in a 10:1 ratio (the popular mixture) developed bladder tumors. To balance these studies, however, dozens of other studies revealed that cyclamate did not induce bladder tumor formation. Nevertheless, FDA banned cyclamate from use as a food additive in 1970, again, due to the Delaney Amendment. With this action, the artificial sweetener market once more belonged to saccharin.

There may still be hope for the return of cyclamate to the American marketplace. FDA is reportedly studying new data that substantiate cyclamate's safety. FDA has also reevaluated the original studies that suggested cyclamates cause cancer in rodents, and reported that the Canadian rat data were in error. It further contended that the strain of rats that responded with tumor growth developed them spontaneously.

The WHO recognizes cyclamates as safe, and recommends an acceptable daily intake of 4 mg/kg. Cyclamate is currently used in over 40 countries.

Aspartame

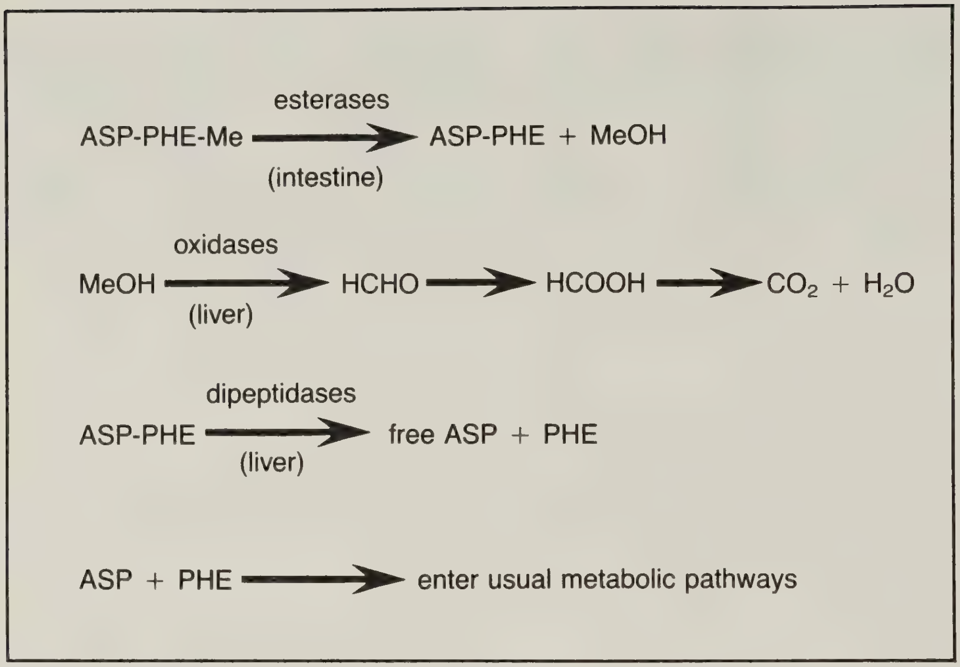
Aspartame was accidentally discovered in 1965 while scientists searched for potential anti-ulcer drugs. Following extensive safety evaluation, it was approved for marketing in 1973.

However, one month later, it was reported that aspartame may cause hypothalamic lesions. FDA, therefore, postponed its introduction date.

Although evidence that aspartame was toxic was not substantiated, the manufacturers of food additives must bear the burden of establishing safety. This marked the beginning of a long investigation that took nearly eight years to complete.

It was finally released in 1981 for sale as a tabletop sweetener and for use in prepared foods such as cold cereals and instant teas, and in 1983 for use in carbonated beverages. It was one of the most thoroughly studied food additives ever to be marketed in the U.S. Today aspartame is sold to food processors as NutraSweet®, and to consumers as Equal®.

Characteristics. Aspartame con-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(intestine)
oxidases
MeOH → HCHO → HCOOH → CO₂ + H₂O
(liver)
dipeptidases
ASP-PHE → free ASP + PHE
(liver)
ASP + PHE → enter usual metabolic pathways

Figure 1. Metabolic pathways of aspartame. ASP: aspartic acid; PHE: phenylalanine; Me: methyl ester; MeOH: methanol; HCHO: formaldehyde; HCOOH: formic acid.

tains two amino acids, l-aspartic acid and l-phenylalanine. The latter is present as its methyl ester. The sweetener is metabolized in the intestine as illustrated in Figure 1.

Both of the amino acids and the methanol are common constituents of many foods as listed in Table 2. A quantity of aspartame equivalent in sweetness to a teaspoonful of sugar yields 8.5 mg aspartic acid, 10.6 mg. phenylalanine, and 2 mg methanol. To compare this with food, an eight-ounce serving of milk contains about fifty times this amount of phenylalanine and aspartic acid. A four-ounce banana contains ten times the methanol.

Individually, the components are not sweet. This is not a problem as long as the aspartame is not degraded. Sweetness is detected only while the substance is in contact with the taste buds on the tongue.

Aspartame is 180 to 200 times sweeter than sucrose. Unlike saccharin, it does not cause an aftertaste. It is only slightly water soluble (1 gm dissolves in 100 ml water at 24°C). Solubility increases with decreasing pH and increasing temperature.

Because it is metabolized to amino acids and methanol, a teaspoonful of aspartame has a food value of 4 calories, the same as sucrose. But, because it is also approximately 200 times sweeter than sucrose, aspartame, which is equivalent in sweetness to a teaspoonful of sugar, has 0.1 calories.

The powdered form of aspartame, Equal®, contains lactose as a bulk former. Equal® contains 2 calories per teaspoonful.

Aspartame is unstable in hot foods. It is, therefore, not suitable for use in items that must be cooked or require sterilization.

It decomposes slowly in beverages, the rate determined by the temperature and pH. The shelf life of a can of carbonated beverage to maintain sweetness is approximately one year.

In dry form, it is stable at 40°C (104°F) for over a year. In alkaline solution, a small amount of aspartame may be converted to a cyclic substance called diketopiperazine. This is neither sweet nor toxic.

The FAO/WHO Expert Committee on Food Additives has suggested 40 mg/kg/day as an acceptable daily intake. The projected consumption for Americans is 34 mg/kg/day. Studies have shown that ingesting 34 mg/kg/day does not raise plasma or erythrocyte levels of aspartic acid or phenylalanine above levels reached after consuming an average meal.

Diketopiperazine is usually present in a concentration of 1 percent or less. Its safe daily intake is 7.5 mg/kg.

Specific Safety Concerns. The aspartic acid component of aspartame is partially metabolized to glutamic acid, another dicarboxylic amino acid. Glutamic acid (as monosodium glutamate, MSG) has been shown experimentally to cause hypothalamic brain lesions in young monkeys. Although articles still occasionally associate aspartame with brain damage due to its decomposition to aspartic acid, this correlation remains to be proven. Some authorities report that the issue is moot in that the sweetener has not been proven to cause central nervous system pathology.

Phenylalanine must be avoided by persons with **phenylketonuria**. This

TABLE 2

Natural Sources of Aspartame Components

Typical Serving	**Aspartic Acid**	**Phenylalanine**	**Methanol**
Aspartame	8.5 mg	10.6 mg	2.0 mg
Meat-dairy			
Hamburger 4 oz	1803.0 mg	882.0 mg	—
Chicken 4 oz	2079.0 mg	907.0 mg	—
Egg 1	542.0 mg	323.0 mg	—
Milk 8 oz	528.0 mg	542.0 mg	—
Vegetables			
Spinach 4 oz	246.0 mg	150.0 mg	—
Lima Beans 4 oz	1745.0 mg	1355.0 mg	trace
Soybeans 4 oz	5512.0 mg	2330.0 mg	trace
Tomato Juice 8 oz	291.0 mg	45.0 mg	47.0 mg
Fruit			
Banana 4 oz	134.0 mg	49.0 mg	21.0 mg
Cherries 4 oz	95.0 mg	16.0 mg	20.0 mg
Pear 4 oz	254.0 mg	13.0 mg	0.04 mg

Source: G. D. Searle and Co., Chicago, IL familial disorder is rare, occurring in 1 of 15,000 persons. Affected individuals have a deficiency of the enzyme phenylalanine hydroxylase. As a result, blood levels of phenylalanine rise, allowing toxic concentrations to enter the brain. Left untreated, symptoms include mental retardation, epileptic seizures, and chronic dermatitis.

Phenylalanine is reported to harm the fetus when pregnant women who are carriers of phenylketonuria ingest it. There is currently no evidence to support this. Studies have clearly shown that when these women ingest aspartame in doses exceeding average, there is no increase, even transiently, in plasma phenylalanine to toxic levels. If victims restrict intake of phenylalanine, they can lead normal lives. Therefore, foods containing phenylalanine must be so labeled. Equal® tablets and packets both state, "Phenylketonurics: Contains phenylalanine."

Phenylalanine is also purported to block the entrance of tryptophan into brain cells. Tryptophan is the precursor of serotonin (5-hydroxytryptamine), a CNS neurotransmitter. A decrease in CNS serotonin level is associated with behavioral abnormalities. Aspartame's effect on tryptophan or serotonin is unclear. Thus, there is no solid evidence that decreased serotonin, if it does indeed occur following aspartame ingestion, causes behavioral changes.

Methanol is also suspected to cause potential toxicity problems to the retina. Methanol-induced damage is due primarily to its oxidation products formaldehyde and formic acid, leading to accumulation of formates.

The amount of methanol in aspartame is insignificant. For example, 36 mg aspartame (i.e., one packet of Equal®) contains 3.49 mg methanol. Eight-ounces of tomato juice or a four-ounce banana contain 47 and 21 mg of methanol respectively. When 200 mg/kg aspartame was ingested in one study (approximately six times the expected daily average intake), no formate was found in blood or urine.

Aspartame is also reported to be safe for diabetics. No abnormalities in glucose tolerance have been reported with diabetics ingesting aspartame. It causes no significant elevation in amino acid content of breast milk at normally ingested quantities. It has been shown to be noncarcinogenic.

Other Sweetening Substances

Some sugars other than sucrose are also used as sweetening agents. They include fructose, sorbitol, mannitol, and xylitol. Some of these contain as many calories as sucrose.

Fructose. Fructose is a metabolite of sucrose. It is 1.2 to 2.8 times as sweet as sucrose and has the same caloric value. Fructose is less readily absorbed than glucose and, therefore, causes a less intense insulin response in well controlled diabetics. Cells still require insulin to transport fructose within them. So fructose-based foods are far from ideal for diabetics.

Sorbitol. Sorbitol is 0.5 to 0.7 times as sweet as sucrose. It is reported to be one of the most frequently used sweeteners, commonly found in breath mints and dietetic candies.

Sorbitol is poorly absorbed from the intestine and, therefore, may ferment there. Ingestion of 5 gm can produce gas and bloating. Twenty grams may cause diarrhea. In fact, sorbitol has been proven to be a safe and effective laxative for OTC use.

Consumers reporting gastrointestinal discomfort from an otherwise unidentifiable cause should be asked about their use of products containing sorbitol. A single sorbitol-containing candy mint may contain as much as 2 gm of sorbitol. Table 3 lists the sorbitol content of various food items.

Mannitol. Mannitol is 0.7 times as sweet as sucrose. It is used to dust chewing gums, and to give bulk to powdered foods.

Xylitol. Xylitol was formerly used in chewing gum to sweeten it and provide a cool sensation in the mouth. It also reportedly reduces the chance for developing dental caries. Toxicological studies show it increases the incidence of bladder stones and adrenal gland tumors in mice fed large doses. Most products that contained xylitol have been voluntarily withdrawn or reformulated by their manufacturers.

TABLE 3

Sorbitol Content of Various "Sugar-Free" Products and Foods

"Sugar-free" gum	1.3-2.2 g/piece
"Sugar-free" mints	1.7-2.0 g/piece
Pears	4.6 g
Prunes	2.4 g
Peaches	1.0 g
Apple juice	0.3-0.9 g

Ref: Hyams JS: *Gastroenterology* 84:30, 1983

New Sweetener. Acesulfame potassium is still under investigation in America but approved for use elsewhere. It is 200 times sweeter than sugar. Its sponsor has petitioned FDA for approval to market the sweetener for use in chewing gum, dry beverage mixes and foods, and as a tabletop sweetener. It is reported that the substance is not metabolized and contains no calories. It is more stable than aspartame and has not shown any toxicity thus far.

The Cancer Issue

The artificial sweeteners, including saccharin, cyclamates, and aspartame, have undergone more intensive testing for safety than any other food additive. By law, if any food additive causes cancer in any laboratory animal, at any dose, by any route of administration, the substance cannot be used in food items. This restriction, known as the Delaney Amendment, is essentially an absolute zero risk standard.

However, many experts believe that the clause is now obsolete. They argue that if it were applied to all chemicals, it would ban most of the world's food supply, many drugs, occupations, recreations, and even the air we breathe. But the results of this testing have still failed to answer all questions that have been raised about the compounds' safety.

The primary deficiency that currently exists is the method of testing for potential carcinogenicity. By definition, cancer tests mandated by FDA require testing at the highest tolerated doses. This means that animals are given the maximum dose that causes no overt toxicity over a 13-week trial. These doses are generally much higher than any human could possibly consume. The issue of whether smaller doses, closer to human intake, should also be studied is currently under consideration.

The issue of whether artificial sweeteners cause cancer cannot yet be settled. The unreliability of animal studies has already been mentioned. Furthermore, there might be human subpopulations or persons of certain ages that are susceptible to carcinogenesis. The role of occupation, smoking, alcohol, and consumption of other foods and beverages such as coffee and tea must also be assessed along with artificial sweetener use.

The increased tumor incidence may be too small to detect in a clinical study, but when extrapolated to a general population, it could be quite significant. There may also be biological systems which are even more sensitive to tumor development than the bladder, but not yet thoroughly studied. Artificial sweeteners may cause tumor formation that requires decades to be fully revealed. Their widespread use in large quantities did not actually occur until the early 1960's when the diet cola craze began.

The role of disease factors needs to be assessed. For example, diabetics use more artificial sweeteners on the average than nondiabetics. It is possible that diabetics *per se*, or diabetics who use artificial sweeteners increase the risk for tumor formation.

Finally, another very important variable has not yet been considered. Most animal studies have employed the sodium salt of saccharin or cyclamate, rather than the less soluble base saccharin or cyclamate. Sodium intake in the animals' diets has not been restricted.

Sodium is a known cause of hypertension, and renal and urinary bladder stones. It is not associated with causing cancer, but it damages renal and bladder tissues, perhaps because it serves as the initial stimulus for saccharin-induced toxicity. Therefore, it should at least be considered and studied.

Overview

Artificial sweeteners have afforded Americans a convenient means of avoiding sucrose and calories. The artificial sweeteners in use today have been thoroughly tested for safety and, when used as directed, are undoubtedly safe. But certain questions concerning their safe use have been raised. Articles reporting new data for and against the use of artificial sweeteners continue to appear in the scientific literature. As is the case with the use of all chemicals, moderation is the best policy.

The ultimate fate of saccharin and cyclamate remains to be determined. Cyclamate appears to have a chance of returning to the American market. Saccharin currently remains on the market under repeated extensions of a Congressional moratorium against the Delaney Amendment restrictions on the sweetener. These restrictions may be lessened to permit its continued availability. On the other hand, if acesulfame potassium continues to remain free of toxicity and is approved for use in the U.S., this may signal the end for saccharin.

Is there value in mixing artificial sweeteners? Perhaps! Detection of sweetness appears to be a function of more than one type of taste bud. For example, the site of detection of sweetness of saccharin is different from that of aspartame. Likewise, cyclamate and saccharin mixed together and tasted seem to have a synergistic effect.

From an economical standpoint for food manufacturers, mixing aspartame and saccharin makes sense. The wholesale cost of saccharin is reported to be less than one-tenth the expense of aspartame. Adding saccharin would permit food prices to remain lower.

Aspartame has been casually associated with several toxic reactions, some potentially serious. However, these charges have not been substantiated. Individuals with phenylketonuria should avoid products containing it.

Consumers should be advised to avoid cooking with aspartame, and adding it to hot foods or beverages that will not be consumed quickly. Some persons report that significant sweetness is lost in the few minutes required for hot cereal or coffee to cool sufficiently for consumption. Up to half of its sweetness may also be lost in a couple hours when aspartame is added to neutral solutions at room temperature.

Aspartame use will continue to expand as more and more manufacturers and food processors add it to their products. Already FDA is proposing a rule which will permit it to be used as a sweetening agent in drug products.

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A regular monthly feature sponsored by the Parke-Davis Center for the Education of the Elderly and the Elder-Health Program, University of Maryland School of Pharmacy. At the conclusion of each series, a sample "Elder-Ed" talk for presentation to community groups, will be outlined.

Cancer, Nutrition, and the Elderly: A Closer Look at Some of the Facts. Part I.

by
Peter P. Lamy, Ph.D.
Madeline Feinberg, PharmBS

Introduction

The American Cancer Society recently launched a new campaign, *Taking Control*, to increase public awareness of cancer risks. Ten steps are identified, which, if followed, may add to longevity. Eight of these 10 steps deal with dietary and nutritional factors! (Table I).

No doubt the current heightened interest is, at least in part, a response to political pressure: quite some time ago, President Nixon declared "war on cancer" and millions of dollars have been spent, and continue to be spent, in an attempt to find cancer cures. Now, there are reports that "we are losing the war on cancer", and perhaps there ought to be much more emphasis on prevention.

It is likely that the increasing emphasis on early detection of breast cancer, the development of home diagnostic kits for colorectal cancer, for example, and a massive, consumer-oriented educational program very similar to that once seen in trying to convince the public that salt restriction is beneficial in the prevention and/or control of high blood pressure.

It probably started with the publication of the "Guide to Food Choices", which gives some commonsense recommendations (Table II). This was followed by a massive public campaign by the Kellogg Company, which trumpeted the benefits of fiber and which is making available, mainly to gastroenterologists, a booklet "Good News", which addresses the role of fiber in cancer prevention. What are the facts? There is no question that among the leading causes of death among those 65 years and older, diseases of the heart rank first (44.6%), malignant neoplasms and cancer rank second (19.5%), followed by cerebral vascular disease. There has been improvement in all 15 leading causes of death for those 65 years old and over except septicemia, suicide, and cancer. It has been suggested that perhaps 35% of all cancers (range: 10 to 70%) in the

TABLE 1

Factors to add to your life
Fresh vegetables (especially cruciferous)
Fiber
Vitamin A
Vitamin C
Weight control
Factors to subtract from your life
Fat
Smoked, salt-cured, and nitrite-cured food
Tobacco (in any form)
Alcohol (excessive)
Exposure to sun

American Cancer Society

US are caused by components of the diet, among them alcohol, coffee, microbial contamination, food processing, and cooking.

Role of Diet in the Development of Cancer

Evidence for the relationship between dietary factors and cancer is determined from three types of studies.

1. Epidemiological studies look at the incidence of cancer in well-defined human populations in relation to known dietary behaviors and other known environmental factors. Early studies concentrated on migratory populations. Current research focuses on controlled studies of individuals and groups. Much of the evidence yielded by epidemiologic studies must be considered indirect evidence, since it is based on the consumption of foods, and not on actual measurement of vitamin intake. Patterns of food intake and other factors may influence observations, hence relationships can only be inferred.

2. Laboratory studies in animals provide a means of systematically observed relationships in epidemiological studies. In addition to verification of observations, the effects of cancer—producing substances has been studied as well with new research technologies being developed for *in vitro* cell studies.

3. Mutagenicity testing determine the ability of substances to cause genetic changes in bacteria and other organisms which may identify cancer-inducing substances. Such testing does not establish carcinogenicity of a substance however. It merely shows it can cause changes in DNA.

Nutrients: Inhibitors/Modifiers of Carcinogens

Specific nutrients are thought to act as inhibitors and/or modifiers of carcinogens by several modes of action:

1. By increasing liver metabolism of the carcinogens, thus increasing the rate of their detoxification
2. By acting as antoxidants
3. By preventing formation of carcinogens
4. By reversing early stages of carcinogenic activity

The "Free Radical Theory of Carcinogenesis" states that free radicals are cancer promoters. The carcinogens are oxidized, and form oxy or peroxy radicals. Metabolism of carcinogens can also produce hydroxyl or superoxide radicals, all of which can cause transformed cells to form. Thus, it was thought that antoxidants would be effective in preventing the formation of transformed cells. Among those investigated are vitamins A, E, and C, the synthetic antoxidants BHA and BHT, and selenium.

Vitamin A: This vitamin may possibly be useful in bladder, breast, GI, lung, nasopharyngeal, oral, and skin cancer. Vitamin A deficiency may enhance the risk to cancer in persons chronically exposed to alcohol and cigarettes. Vitamin A inhibits proliferation of transformed cells and excess vitamin A inhibits tumor formation.

Preformed vitamin A is obtained from animal food sources, while carotenoid compounds are obtained from green and yellow vegetables. The proposed protective effect is apparently better when beta carotene is consumed. Massive vitamin A or beta carotene intake, however, does not increase serum retinol levels, except in frank deficiency. There is need to consider possible vitamin A toxicity.

Vitamin E: This vitamin is thought to be an important intracellular antoxidant which can reduce mutations in some bacterial testing systems. It may protect against some carcinogens and may inhibit chemical chromosomal damage. However, proof of these assumptions is still lacking.

Epidemiologic studies are lacking regarding the effects of Vitamin E deficiency, since this vitamin is widely distributed in common food sources (vegetable oils, whole grain cereals, eggs).

Vitamin C: Conversion of nitrites to N-nitroso compounds is prevented by Vitamin C and Vitamin E. These two vitamins do not block the formation of endogenous nitrosamines, but do reduce substantially their formation from dietary nitrate and proline. A dose of 500 mg QID of vitamin C has been suggested, and a dose of 400 IU daily of Vitamin E. Reduced risk to gastric and esophageal cancer is associated with Vitamin C.

Synthetic Antoxidants: BHA (butylated hydroxyanisole) and BHT (butylated hydroxytoluene) have long been used as antoxidants. Both apparently can protect against chemically induced tumors by accelerating catabolism and excretion of carcinogens (40). BHT may be superior to BHA. A recent report points out that large doses (4 g) of BHT can cause severe epigastric pain and cramping and have caused brief episodes of loss of consciousness.

Selenium: There is considerable evidence that increased intake of selenium decreases cancer risk. Selenium apparently inhibits growth of chemically- or virally-induced and transplanted tumors. It may modify the metabolism of carcinogens and decrease proliferation of neoplastic cells.

Since a low selenium status apparently enhances cancer risk, selenium intake should be helpful. However, a specific dose has not yet been identified, nor have biochemical indicators of selenium toxicity. The nutritional dose for selenium ranges from 50 to 200 mcg, while the pharmacologic dose exceeds 600 mcg. It is also not clear which form of selenium would yield the best results: selenate, selenite, or selenium yeast.

* * * *

Part II. will deal with risk factors associated with dietary fat intake, caloric intake and fibers, and the implications of malnutrition in treating cancer.

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Speakers Bureau—A Recap

by
Dave Banta, Executive Director

In June 1982 the Centennial Celebration Committee of the Maryland Pharmaceutical Association recommended the establishment of a Speakers Bureau as the association centennial project. The Elder-Ed Program of the University of Maryland School of Pharmacy was adopted as the model for this program and a series of five "sample" talks were published in outline form in the June 1982 issue of this journal.

It is four years later and we continue to have an active Speakers Bureau in this Association. The majority of program requests are coming from the elderly community groups. Due to the interest of the community and the responsiveness of our pharmacists in meeting their requests, we have reprinted and updated the Elder-Ed series. The following talk outline on vitamins and nutrition represents the last in the original series to be reprinted.

However, our monthly column, "Timely Topics" dealing with current issues of disease management, drug therapy, wellness and prevention for elderly, represents this Association's ongoing commitment to encourage and support pharmacists to stay updated in important issues and to bring this timely information to their respective communities. At the end of each series presented in "Timely Topics" a sample Elder-Ed talk on the issue will be outlined. By using "Timely Topics", we hope to maintain our dynamic Speaker's Bureau and promote the visibility of pharmacy and its practitioners in the state of Maryland.

Nutrition, Vitamins, and Minerals for the Older Adult . . .

or, "A poor diet plus vitamins is still a poor diet."

Quote by Art Ulene, MD

I. INTRODUCTION
  1. Introduce self
  2. Involve audience. Ask questions
    —"How many people here take a vitamin every day?"
    —"What made you decide to take a vitamin (and/or mineral)?"
    —"Where do you purchase your vitamins?"
      pharmacy
      health food store
      grocery
      mail order catalog

II. WHY ARE PHARMACISTS CONCERNED WITH NUTRITION, VITAMINS, MINERALS
  - misuse (cover up underlying problem by treating with vitamin)
  - toxicity (large doses may cause harm)
  - wasteful (may not need supplement)
  - may interact with medications
  - who, in health care system, is knowledgeable about vitamins, minerals, nutrition that you can readily ask?
    doctor nurse
    pharmacist dietician

III. VITAMINS: FOOD SUPPLEMENTS OR DRUGS?
  1. Two points of view:
    —vitamins are dietary supplements not subject to strict controls imposed on drugs
    —vitamins viewed as drugs and should only be used to prevent a deficiency state or to treat a deficiency state
  2. Why the controversy
    —our knowledge on the subject of human nutrition is still limited
    —most health-care providers do not study nutrition in school
    —deficiency state may be difficult to detect (subclinical effects vs. overt symptoms of disease)

IV. VITAMINS ARE NOT A SUBSTITUTE FOR GOOD NUTRITION
  (refer to pamphlet *Vitamins are Not Enough*)
  1. Components of good nutrition
    —What needs to be eaten daily: 7 basic food groups
  2. Vitamins are not pep pills, if used in excess they may be dangerous

V. VITAMINS:

1. Definition—organic chemical substances (contain carbon). Only very small amounts required for health maintenance. Vitamins are a part of enzymes which perform essential chemical reactions in the cell.
2. Two major classes of vitamins:
   - —water soluble: need to replace daily (some controversy) includes all B vitamins Vitamin C
   - —fat soluble: stored in fatty tissue of body Vitamins A, D, E, K
3. Define RDA—guidelines for optimum nutrition provided by Food and Nutrition Board of the National Academy of Science/National Research Council and by the Food and Drug Administration.
   - —based on age, sex weight, height, other special conditions (pregnancy, lactation)
   - —represent highest average amount of nutrient that will meet needs of most healthy Americans
   - —sufficiently high to account for individual variability, illness, stress
   - —no RDA established for elderly (except for calorie requirements). Oldest age grouping is "over 51 years"
4. Megavitamins
   - —extremely high (10× RDA or more) doses, often used to prevent or cure disease
   - —Do they? No!
   - —No good scientific studies as proof, but in popular literature there are many theories

V. SOME THOUGHTS ON SELECTED "GLAMOUR" VITAMINS

A. Vitamin C
1. Uses
2. When to avoid
   - —gout
   - —history of kidney stones (oxalate type)
   - —if testing urine for sugar
3. Know latest information on Vitamin C and common cold
4. Explain how Time-Release Vitamin C works
5. Explain difference between "natural" and "synthetic"
   - —bioflavanoids
   - —rose hips
6. Discuss difference in price and true value
7. Rebound scury when suddenly stopping high dose therapy

B. Vitamin A
1. Currently most popular "anti-cancer" vitamin (See "Timely Topics" on Nutrition, Diet and Cancer)
2. Eating cooked yellow vegetables seems to provide some protection against certain types of cancer
3. Different forms of Vitamin A may make a difference in response of individual (carotene and retinols)
4. Toxicities with high doses
   - —headache
   - —bone pain
   - —loss of appetite
   - —skin and cornea may turn yellow
   - —hair loss
   - —cracked lips
   - —scaly skin

C. Vitamin D
1. Uses
2. Prescribed by doctors for certain bone diseases e.g.
   - —rheumatoid arthritis
   - —Paget's disease
   - —with calcium for osteoporosis
3. Elderly, homebound may have true Vitamin D deficiency
4. Excessive doses of Vit D may cause
   - —calcium deposits in joints, arteries, kidneys
   - —may increase blood pressure

D. Vitamin E
1. Uses
2. Be prepared to discuss current fad (anticancer, circulation, "youth vitamin")
3. Avoid daily amounts in excess of 400 I.U. Excessive doses may cause
   - —flu-like symptoms
   - —mental confusion
   - —disorders of fat metabolism
   - —anti-coagulant effect
   - —headache, nausea

E. Vitamin K
- —elderly persons, particularly those on anticoagulant medications, should be aware of Vit. K content in foods, particularly certain vegetables, tea

F. Vitamin B 12
- —usually only used for pernicious anemia and given by injection
- —elderly use as placebo

G. Vitamin B 6—pyridoxine
1. High doses of this vitamin, once thought safe, can cause neurological symptoms: numbness, ataxia.

H. Nicotinic Acid
1. High doses for long periods implicated in liver damage.

VI. "NEW VITAMINS"

A. Caution elderly, from time to time "new" vitamins are introduced with fabulous claims
1. None shown to be effective in meeting claims
2. None are actually vitamins

THE MINERALS

VII. MINERALS
- 1. Definition: These are *essential* substances needed for health maintanence. They are inorganic substances. Some are required in comparatively large amounts (macro-elements): others in very small amounts (trace elements)
- B. Balanced diet—will provide all essential minerals and trace elements in sufficient amounts
  - 1. An exception is calcium! ¾ of American diets do not meet the RDA for calcium. And, RDA is probably too low!

VIII. SOME THOUGHTS ON POPULAR MINERALS
- A. Iron
  - 1. Iron is not a pep pill, it cannot give more energy
  - 2. Indications for iron therapy
    - —anemia (deficiency which occurs due to blood loss)
  - 3. Problems taking iron
    - —constipation
    - —diarrhea
    - —irritating to stomach
    - —may need to avoid if history of ulcer
  - 4. Type of products available (long-acting, liquid, injectable
  - 5. Monitoring for effectiveness of iron therapy
- B. Calcium (see Timely Topics, June 1986 *Maryland Pharmacist* for extensive discussion on indications, products)
  - 1. Indications for supplements
  - 2. When to give with Vitamin D
  - 3. How to take
  - 4. Selection of product, costs
- C. Potassium
  - 1. Discuss potassium deficiency caused by diuretic therapy. Only detected by blood test!
  - 2. Compare food sources to prescribed potassium supplementation
  - 3. Discuss consequences of what may happen when potassium is taken without medical supervision
- D. Zinc
  - 1. Recently popularized due to role in reproduction, normal skin and hair growth, immune function, appetite
  - 2. RDA for zinc 10 mg
    Excessive amounts can interfere with absorption of calcium, iron, magnesium and other essential minerals
  - 3. Need to avoid excessive supplement of one mineral since *balance* is needed.

Conclusion: RECOMMENDATION:

A one-a-day type vitamin supplement, with or without minerals in recommended in addition to a well-balanced diet. The supplement is recommended as an "insurance policy" in the event all essential nutrients are not taken on a regular basis.

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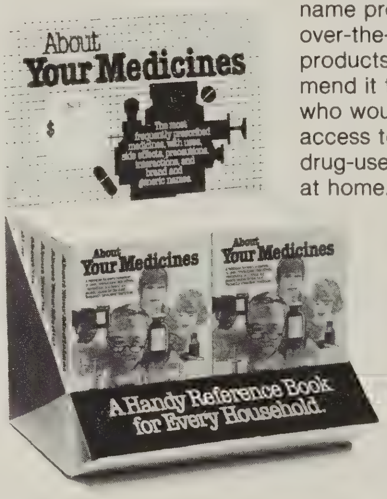
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William J. Kinnard, Jr., Dean of the University of Maryland School of Pharmacy, (left) shows off the newly dedicated display in the School which depicts the old Sharp & Dohme Company which was founded in Baltimore to Frank M. Coistner, Vice President for Merck, Sharp & Dohme.

martin's
EUDOWOOD

The Alumni Association held its Annual Graduation Banquet on May 22, 1986 in Baltimore. Outgoing President Karen Lewis (left) receives an award from current President Tom Williams.

The Alumni Association's Honored Alumnus this year is George Voxakis (left) and he receives the presentation from Past President Melvin Rubin (right). Voxakis is also President of the Baltimore Metropolitan Pharmaceutical Association and the Maryland Pharmaceutical Association.

The University of Maryland School of Pharmacy Class of 1936 celebrated their fiftieth anniversary at the Graduation Banquet.

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COMMERCIAL NONPROFITS

A Threat to Free Enterprise and Public Health

Few issues have galvanized the American business community in recent years quite like unfair competition from commercial nonprofits.

Both the numbers and economic influence of nonprofit organizations have grown tremendously in recent years. Their income now represents more than 9 percent of GNP—three times what it was after World War II. And those figures don't even include sales by tax-exempt entities such as universities and state institutions.

All these commercial nonprofits enjoy a variety of benefits not afforded their taxpaying competition, including special treatment or exemption from Social Security payments, unemployment insurance, minimum wage laws, securities regulation, antitrust laws, postal rates, and more. It's even been demonstrated that commercial nonprofits tend to concentrate where taxes are the highest.

PERVASIVE PROBLEM

The problem of unfair competition by commercial nonprofit organizations is pervasive. Many trade associations have banded together in the Business Coalition for Fair Competition (BCFC) to combat the rapid and unregulated expansion of government and nonprofit entities into commercial markets. Among the members of BCFC are associations representing travel agents, engineers, nurserymen, bus owners, and independent retail pharmacists. NARD serves on the BCFC Executive Committee.

Businesses represented in the upcoming White House Conference on Small Business have also made unfair competition by commercial nonprofits a top priority. Overall, the issue of unfair competition by commercial nonprofits is #3 of the top issues to be addressed at the conference.

The Small Business Administration has also joined in the struggle. It has published a detailed report on the problem, *Unfair Competition by Nonprofit Organizations with Small Business: An Issue for the '80s.* In his appearance at NARD's 1985 legislative conference, SBA Office of Advocacy Chief Counsel Frank Swain told pharmacists that "when a nonprofit institution, on a continual, regular basis, decides it wants to sell something, whether it's related or unrelated to its principal field of endeavor, they at least ought to do it under the same rules and regulations that everybody else in the small business community has to live with."

PUBLIC HEALTH THREAT

While unfair competition from commercial nonprofits is a problem for many industries, its manifestation in the prescription drug market goes beyond fair competition and free enterprise: it threatens public health.

The root cause of the subterranean drug diversion market is the abuse of the 1938 Nonprofit Institutions Act by commercial nonprofit organizations. The 1938 act—passed to provide an exemption to the Robinson-Patman Act for truly charitable institutions—was not intended to reward certain competitors while bankrupting others or to provide the catalyst for an illegal, life-threatening marketplace for diverted drugs.

And yet that is precisely what has happened. The Nonprofit Institutions Act today is abused by openly commercial nonprofit entities to protect themselves from discriminatory pricing crimes under the Robinson-Patman Act. And it is that exemption that drug diverters are now exploiting to reap enormous, illegal profits from the nation's drug distribution system.

In short, if we can put an end to discriminatory pricing, we will put an end to the diversion market. They are inextricably linked.

LEGISLATIVE SOLUTIONS

Landmark legislation, H.R. 4820, to put discriminatory pricing behind us once and for all has recently been introduced. Oversight Subcommittee Chairman John Dingell's (D-MI) bill will, among other remedies, ban the sale of prescription drugs or samples by nonprofit institutions not for their own use, as well as the sale of drugs donated or supplied at a reduced price to charitable institutions.

A bill complementing that legislation has been introduced by Rep. Thomas Luken (D-OH). The measure would require annual registration with the FDA of all nonprofit entities engaged in the provision of health services and the dispensing of prescription drugs that wish to qualify for the charitable exemption to the Robinson-Patman Act as defined under the terms of the 1938 Nonprofit Institutions Act.

These actions by Congress are important steps in doing away with the threat to public health and fair competition created by discriminatory pricing. But there is much political legwork yet to be done to eliminate other forms of unfair competition by commercial nonprofit institutions.

BCFC has published a guide, *Unfair Competition in the States: How to Combat Competition from Nonprofit Business Ventures,* to help you address this problem. It includes detailed information on how to fight unfair competition in your state. If you would like a copy of this valuable resource, send $5 to Unfair Competition, National Association of Retail Druggists, 205 Daingerfield Rd., Alexandria, VA 22314.

FYI, a monthly perspective on topics of interest to pharmacists, is provided as a service by the National Association of Retail Druggists.

Classified Ads

Classified ads are a complimentary service for members.

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calendar

Aug 8–9—South East Regional States Convention, Nashville, Tennessee
Aug 14–15—Affiliated States Meeting, APhA, Washington, D.C.
Sept 28–Oct 2—NARD Annual Convention, Louisville, Kentucky
Oct 26—Alumni Association Dinner
Nov 13–16—ACPE Convention, Chicago, Illinois

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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Gabriel E. Katz	Ph. G. 1934
Charles R. Kesmodel	Ph. G. 1932
Leonard H. Kramer	Ph. G. 1932
Godfrey Kroopnick	Ph. G. 1926
Jennie Kroopnick Leberman	Ph. G. 1922
Harold Lipsky	Ph. G. 1927
Hans Morgenroth	B. S. 1948
Samuel Morris	Ph. G. 1934
Alexander J. Ogrinz, Jr.	Ph. G. 1934, B. S. 1935
Leo C. Rettaliata	Ph. G. 1918
Leonard M. Rice	B. S. 1949
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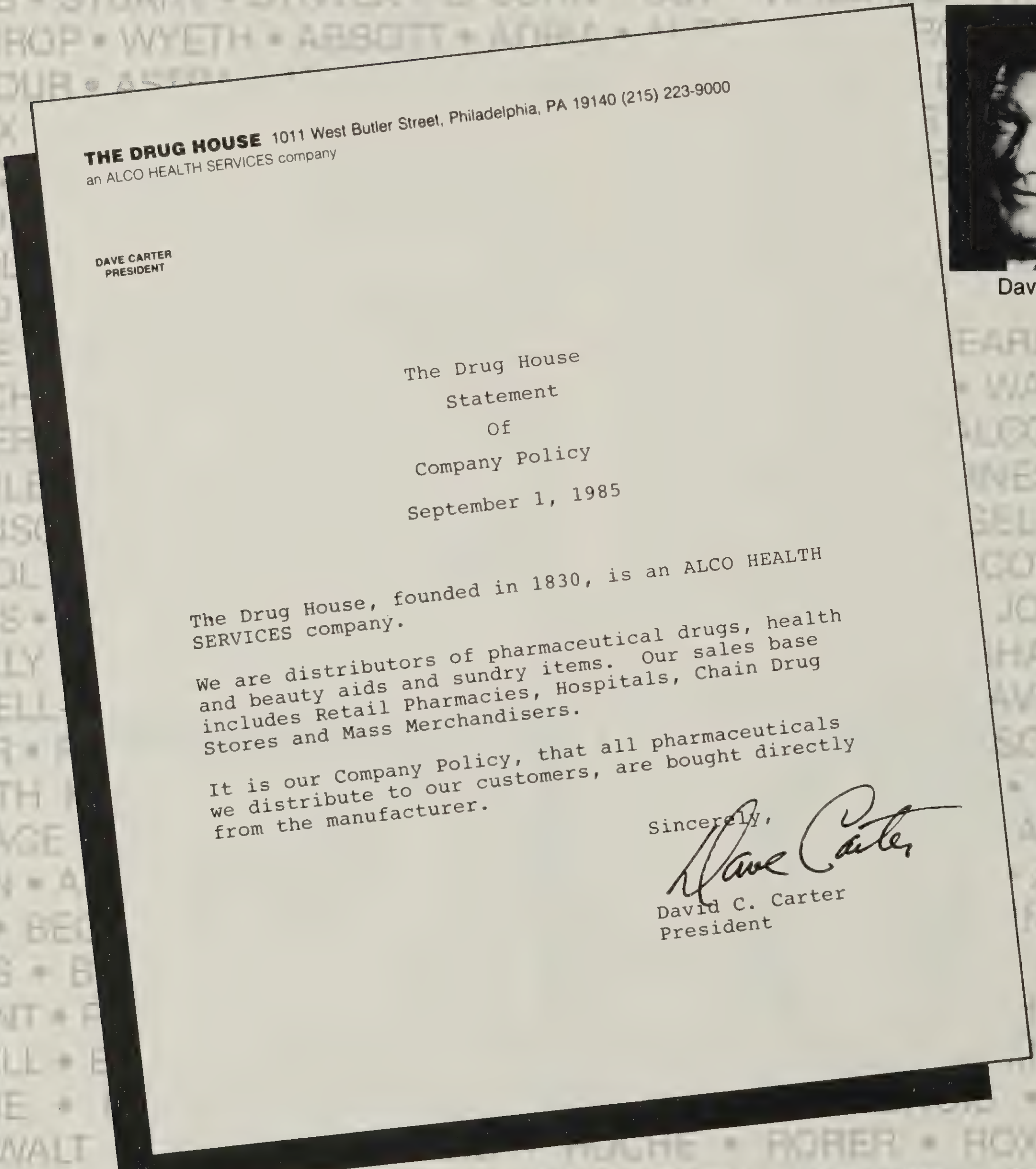

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PRESIDENT

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Of
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Dave Carter

David C. Carter
President

David C. Carter,
President

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Advising Consumers on Chemical Insect Repellents

— Thomas A. Gossel
— J. Richard Wuest

Annual Report of the Maryland Board of Pharmacy

Pharmacy in Long-Term Care

— Peter P. Lamy

Nurse Practitioners: Who we are and How we function

— Linda Foster

1986 Lilly Digest

Timely Topics: Cancer Nutrition and the Elderly, Part II

TALK ABOUT
PRESCRIPTIONS
MONTH

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SEPTEMBER, 1986 VOL. 62 NO. 9

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President's Message

Air Traffic Controllers and Pharmacists—Much in Common?

This may seem a strange analogy, but stop and think for a moment how these two seemingly different occupations are becoming increasingly similar. Obviously, in both cases, people's lives directly depend on how well you perform.

Even more obvious is that the word pharmacist does not conjure up a particularly glamorous image. Instead, each week on average, there are new rules and regulations to which a pharmacist must comply: Which manufacturer's product to dispense? What quantities may he dispense? Who is an authorized prescriber? Is the patient eligible? Is it a ''reimbursable'' medication? What is the allowable fee? Etc., etc., etc.

When all of the above has been determined, he may then fill the prescription and counsel the patient, which I thought was our primary function. When there is time, the paperwork is completed and the wait begins for reimbursement (which could come in weeks or months—if at all). To add to this stress, there are questions to answer on the phone, plus other patients who come in just to ask advice. Added still is the pressure to fill more and more prescriptions in less and less time. Is it any wonder that pharmacists are ''burning out'' at a younger age? See any more similarities? One rarely sees a practicing 70-year old pharmacist, a common sight just a few years ago. The shortage of pharmacists which presently exists in Maryland will only be compounded by pharmacists having shorter careers.

I think you will agree that my analogy is not quite as strange sounding as it first appeared. Let us hope that it does not take a major catastrophe for us to awaken to the danger that is growing among us.

George C. Voxakis
PRESIDENT

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 8

Advising Consumers on Chemical Insect Repellents

by **Thomas A. Gossel, R.Ph., Ph.D.**
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss theories on factors that attract and repel insects from humans;
2. outline factors that contribute to increasing the efficacy of chemical insect repellents.

in the service of pharmacy

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Objectives

At the conclusion of this lesson, the successful participant should be able to:

1. list the major factors that enhance chemical insect repellent activity;
2. differentiate between the different chemical insect repellent products;
3. explain the meaning of the FDA restriction on the use of thiamine as an oral insect repellent;
4. state the mechanism of action of insect repellents;
5. list the major adverse effects associated with systemic absorption of DEET.

Man has battled insects since earliest recorded history. Besides being very annoying, insects carry many diseases which are harmful to humans.

Insecticides have been widely used to help control pests, but their actions are limited. While a number of insect species have been almost totally eliminated, many have survived and are resistant to the chemicals intended to control them.

Chemical repellents offer an alternate means of reducing the incidence of insect bites and stings. Available repellents are active against common disease-carrying pests such as mosquitoes and ticks. They are used more to alleviate the annoyance of insects rather than to prevent disease.

Repellents are more effective against biting insects such as mosquitoes than against the stinging insects such as bees, wasps, and hornets. These stinging pests actually cause more serious reactions which may lead to anaphylaxis. Also, repellents do not repel spiders.

Since pharmacists are frequently asked questions about repellents, this month's lesson will examine chemical insect repellents. The uses, limitations, similarities, and differences among the various products will be discussed. Their safety and adverse reactions will also be reviewed. The lesson will list the various physical, chemical and biological factors known to affect repellent protection times.

Chemical Repellents

Chemical insect repellents are volatile substances that reduce the attractiveness of human skin to insects. Aside from possibly frustrating hungry insects, repellents do not harm or kill them. Ideally, they should keep the insects from landing on the skin. Some repellents achieve this. Other repellents allow the insect to land on the skin but not bite. While the mechanism of action is not completely understood, it is proposed that the repellent activity is achieved by disguising human body odors from insect detection.

Currently, there are three chemicals used as insect repellents in the United States (see Table 1). They are **diethyl-m-toluamide** (DET, DEET), **ethyl hexanediol** (ethohexadiol), and **dimethyl phthalate**.

Consumers frequently express personal preference for OTC products containing specific ingredients, while others request direction in choosing an insect repellent. Since the U.S. Department of Agriculture has identified DEET as the most powerful, best all-purpose repellent, one may feel confident in recommending it.

TABLE 1

Chemical Insect Repellents

Repellent	**Representative Product**
Diethyl-m-toluamide	OFF products
Dimethyl phthalate	in some Cutter products
Ethyl hexanediol	6-12 products

DEET is the standard against which all other repellents are compared. It is reported to possess greater resistance than the other chemical repellents to removal by abrasion and washing off in water.

All three chemical repellents are useful against a wide variety of mosquitoes, chiggers, gnats, flies, and ticks. These are the most common insect pests in the U.S. and Canada. Unfortunately, none of these repellents protect for more than a few hours and all require repeated application for continued effectiveness.

Various volatile oils including citronella, bergamot, cassia, clove, eucalyptus, lavender, pennyroyal, turpentine, and wintergreen have been used to repel insects. These substances purportedly offer repellent action primarily against mosquitoes and flies. At best, this action appears to be minimal. None is acceptable for widespread use in high concentrations directly on the skin since such application runs the risk of causing adverse reactions.

What Attracts Insects to Humans?

Mosquitoes are believed to be attracted to humans by a variety of factors: sweat, moisture, heat, odor, and carbon dioxide. The insect's sight is important, but to a lesser degree. It may play a greater role if the target is in motion.

The most important factor for attracting mosquitoes from a distance is body odor, which is partly determined by sweat. As long as the wind is blowing away from the insect and toward the individual, mosquitoes at a distance will be little attracted. If they are downwind from an individual, the mosquitoes will travel upwind from as far away as 30-feet. For shorter distance attraction, mosquitoes are allured more by moisture, then carbon dioxide, and then heat.

There is a lipid component of sweat that seems to repel mosquitoes. When this substance is removed from sweat, mosquitoes become more attracted to humans. If this finding is significant, variations in the amount of this component of sweat may help explain why some people are more susceptible to mosquito bites than others.

Determining the identity of this substance and manufacturing it on a large scale may help lead to the development of an effective systemic repellent. Or, the substance may be incorporated into OTC topical repellent products to enhance their efficacy.

But the attraction of insects to humans is more complex. There are still many unanswered questions. The specific mechanism of attraction remains unknown.

Historical Considerations

More than 25,000 chemicals have been tested for insect repellent activity by the U.S. Department of Agriculture since 1942. At that time, the Department initiated a widespread search for chemicals that would effectively repel disease-transmitting insects. The greatest interest was in finding chemicals that would protect American military personnel stationed in tropical or subtropical climates.

Commercial uses were not part of the original program. During World War II, for example, U.S. armed forces lost four times as many productive days of action to diseases as they did to battle wounds. Anthropod-borne diseases were responsible for the largest number of lost combat/work days.

Chemical compounds were chosen at random from shelves of various commercial, governmental, or college laboratories, and subjected to screening programs to determine whether they reduced the attractiveness of human skin to insects. Others were specifically synthesized with definite chemical characteristics in mind which were thought to be important to effective repellent activity.

While approximately 2 out of every 1000 chemicals tested showed promise of effectiveness *in vitro*, few of them met all of the criteria which were identified for insect repellent activity on humans (see Table 2).

The emphasis on toxicity is evident in that repellents are frequently used over large areas of the body for prolonged periods of time.

Individual Variances

A commonly expressed complaint is that insect repellents do not work, or do not work as well on some individuals as they do on others. This may be due to improper use of the products. Correctly used, the chemical repellents listed in Table 1 are usually effective for most individuals. Consumers may achieve better success with insect repellents if they are aware of the following factors which influence product effectiveness.

TABLE 2

Criteria for Safe and Effective Chemical Insect Repellents

- Effective against a wide variety of insect species
- Feel comfortable and cosmetically acceptable
- Inoffensive odor
- Withstand removal by wiping and abrasion, hot and humid weather conditions, and sweating
- Stable in sunlight
- Long lasting action
- Harmless to clothing, eyeglasses and jewelry
- Nonirritating and nonallergenic
- Nontoxic

Concentration. The concentration (amount) of repellent applied to the skin is the primary consideration for effectiveness. Repellents listed in Table 1 are safe when applied to the skin as directed on their labels. The concentration remaining on the skin over the period of time following application is a very important consideration.

Repellents form a protective barrier on the skin. Tests have shown this vapor barrier extends to less than 4 cm from the site of application. Following application, mosquitoes may still be attracted to human skin, but they will not bite.

For more volatile compounds, the greater the distance from the site of application, the more effective the product will be. Since the protective barrier extends 4 cm at most from the site of direct application, all exposed areas of skin must be treated if protection is to be complete. Additionally, their benefit is countered somewhat by loss of protective action due to evaporation from the skin.

Abrasion/Wiping. Removal of repellent by abrasion or wiping accounts for the greatest loss of activity. Even with moderate movement, the repellent will be wiped from the skin, especially at the collar and sleeves. With more intense physical activity such as work or exercise, removal is hastened. Clothing, knapsacks or similar articles may rub across the skin several hundred times within a few minutes. The more intense the physical activity and the greater the friction, the more frequently greater amounts of repellent should be applied.

Sweating. As discussed earlier, sweat is one of the major attractants of mosquitoes and many other insects. Sweating will dilute repellents and hasten their evaporation. When sweating is profuse, the repellent action is lost even more quickly. Repellents are still active when diluted, as long as their concentration on the skin remains high enough.

Loss From Water Wash-off. Fishermen, campers, and persons who are subjected to frequent bathing or rain showers are susceptible to rapid repellent removal. None of the currently available repellents resist water wash-off. They are quickly diluted and rinsed from the skin.

Environmental Temperature. Since chemical repellents are volatile, there is a direct correlation between ambient temperature and rate of repellent removal by evaporation. In one study, the effect of DEET with temperatures between 25°C to 50°C was investigated. A statistically significant negative correlation was found between temperature and time. It was demonstrated that for each 10°C increase in temperature, repellent protection time was reduced by fifty percent. In other tests, ethyl hexanediol withstood heat the least. When all factors are kept equal, protection time is much longer at room temperature than at higher temperatures.

Wind Velocity. Wind velocity and air currents are also important to repellent activity. This was demonstrated with DEET used as the control repellent. When the repellent was applied at room temperature (26°C) with normal air currents, it provided a protection time of 200 minutes against mosquito bites. When the same concentration was applied and wind velocity was increased to 192 meters/minute, protection time decreased to 73 minutes. So when repellents are used in high wind velocity, they will need to be reapplied more frequently.

Minimum Effective Dose (MED). The MED is the smallest concentration of repellent which, when first applied, will inhibit insect biting. The values reflect relative repellent potency and are used in comparative studies when newer compounds are tested against older ones.

However, these values may have more theoretical than practical application. For example, Table 3 lists MED values and repellent protection times for the three chemicals in popular use and three others also reported to have repellent activity. There was no positive correlation noted.

TABLE 3

Protection Time of Several Repellents Applied on the Same Subject with Corresponding MEDs*

Repellent	Protection Time ± SE	MED ± SE
DEET	4.2 ± 0.3	0.016 ± 0.003
Triethylene glycol monohexyl ether	6.5 ± 0.7	0.032 ± 0.004
Hexamethylene butane sulfonamide	10.0 ± 1.1	0.016 ± 0.006
Dimethyl phthalate	1.3 ± 0.4	0.064 ± 0.028
Ethyl hexanediol	1.8 ± 0.5	0.064 ± 0.012
Indalone	1.5 ± 0.0	0.064 ± 0.0

Protection time in hours; application at 0.16 mg/cm^2; MEDs in mg/cm^2

*Modified from: Maibach HI et al: Use of insect repellents for maximum efficacy. *Arch Dermatol* 109:32, 1974

However, a negative correlation could be due to numerous factors. For example, chemical repellents bind to the skin and are absorbed at different intensities and rates. They also evaporate at different rates.

Biological Variation. Individuals vary as to the amount of insect repellent protection they receive from any given compound. When all physical factors of temperature, air, velocity, etc., are kept constant, protection times will vary.

For example, the repellent protection times of dimethyl phthalate applied at a concentration of 8 mg/in^2 was studied on two individuals. All of the other variables were held constant. Protection times were 52 minutes on one subject and 200 minutes on the other.

Repellent Safety

Adverse reactions to insect repellents are rare and infrequently reported when the products are used as directed. These effects include local reactions such as itching and tingling, minor dermal lesions and desquamation (sloughing off of skin in scales). Sensitivity reactions are rare.

Repellents can be absorbed through the skin. Approximately half of an applied dose of DEET that is not lost through evaporation, abrasion, wash-off, etc., is reported to be absorbed within six hours. Metabolites have been detected in adipose and dermal tissues for one to two months.

Several serious reactions have been reported following prolonged application of large quantities of DEET. One patient, a 5-year-old girl, developed neurological toxicity including tremors and convulsions from nightly applications of a 10% spray product for almost three months. Her parents indicated that they had carefully followed directions on the label, and had not applied the product to any mucous membrane. She died 24 hours after onset of symptoms. At autopsy, her brain showed intense generalized edema.

Another patient, aged 18 months, drank an unknown quantity (probably small) of DEET solution. She was admitted to the hospital with tremors and generalized body seizures. She survived but her convalescence was slow.

Other repellents also appear to cause reactions ranging from irritation on application to coma following ingestion.

Is Thiamine An Effective Oral Insect Repellent?

Some consumers and authors in the lay press feel that oral thiamine is an effective insect repellent. The Food and Drug Administration and scientists who have studied it say no. Who is right?

Over the years a variety of substances have been taken internally to offer repellent protection against insect bites, mainly from mosquitoes. Sulfur and garlic, for example, have been used to impart an offensive odor or taste to the skin to ward off mosquito attack.

The best known and perhaps most widely used substance taken internally to repel insects has been thiamine (vitamin B$_1$). In a study published in the medical literature more than four decades ago, oral or parenteral doses of this substance were reported to repel mosquitoes. The investigator noted that nine patients, including adults, children, and infants were protected. Another trial three years later extended the protection spectrum to fleas.

Other studies since then have added more credence to the original observation. In some of them, thiamine doses upwards of 300 mg/day, and in one study up to 1 gm/day, have afforded apparent relief. The thiamine therapy was initiated one to two weeks before, and continued during periods of exposure to insects.

However, the reports published over the past 40 years have lacked scientifically acceptable study design. Few have utilized placebo controls needed to assure accurate results of effectiveness.

Thiamine is one of the B-complex vitamins that is generally safe even when taken in high doses. It is water soluble and quickly eliminated from the body in the urine. Its activity in repelling mosquitoes is reportedly due to its deposition under the skin. This is said to impart a disagreeable odor and/or taste that is repulsive to mosquitoes.

Over the years, thiamine has been marketed in several OTC products promoted for oral use to repel mosquitoes. This places it in the "drug" rather than "vitamin" category, because a therapeutic claim is made. Therefore, products containing thiamine that include this claim have come under the scrutiny of an FDA/OTC advisory panel.

Specifically, the available data relating to use of thiamine as an internal insect repellent were carefully and thoroughly reviewed by the FDA Advisory Review Panel on OTC Miscellaneous Internal Drug Products. The panel reported to FDA that thiamine is safe in daily doses up to 40 mg, but it believed that it was inappropriate to administer higher doses than were necessary to maintain human dietary requirements.

Nevertheless, FDA responded to the panel's report and placed the vitamin in Category II (safe, but not effective). This means that manufacturers can no longer claim effectiveness for oral thiamine as an insect repellent. The rule does not prevent the sale of thiamine for this purpose. Rather, it makes it unlawful for manufacturers or distributors to make the claim.

Summary

At the present, there is no chemical that will repel insects economically from a large geographic area. So the most practical approach is to apply an insect repellent product to all skin areas that will be exposed to biting insects.

Topically applied insect repellents are safe and effective. To achieve maximal protection against insect bites, the products must be applied in sufficient concentration. They require frequent reapplication when the various factors listed earlier come into play. Ineffective results are generally due to incorrect use of the product. A list of guidelines for consumers is included in Table 4.

TABLE 4

Consumer Advice for Insect Repellents

1. Apply this product generously to all areas of exposed skin. In areas of dense insect populations, spray it on clothing also.
2. During heavy sweating, or if it is raining, apply this product more frequently.
3. Generally, more concentrated products are better. Thus, sprays are less effective than lotions or sticks.
4. Do not spray this product directly on the face. Apply it to hands and transfer it to the face.
5. Do not use this product on any mucous membrane (lips, nose, etc.). Do not apply it on or near a cut or bruise. Do not get it in the eyes.
6. Keep this product out of the reach of children.

Combining two or more ingredients may extend the spectrum of action slightly, by an additive rather than a synergistic effect. When used against common insect species encountered from Alaska to Panama, effectiveness is usually just as significant from using increased concentrations of any one product, or applying it more frequently, as it is to combining ingredients.

The best protection is obtained from the most concentrated products. Generally, lotions, sticks, and solutions are more concentrated, and thus more effective, than sprays.

Repellents are applied directly to the skin. They can also be applied to clothing in heavily infested areas.

Vacationers could be counseled to purchase their insect repellent where they are traveling so the product will be specific for the insects in that area.

Drugs and cigarettes may not mix... do your patients know?

The American Pharmaceutical Association and the National Cancer Institute introduce a new program to help you explain smoking-drug interactions to your smoking patients . . . and to help them break the habit.

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HELPING SMOKERS QUIT KIT
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Office of Cancer
Communications
National Cancer Institute
Building 31, Room 10A18
Bethesda, MD 20892

Annual Report of the Maryland Board of Pharmacy

1985–1986

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable Harry Hughes, Governor of Maryland and to the Maryland Pharmaceutical Association. This is the eighty-third report to the Governor and the seventy-third report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the fiscal year ending June 30, 1986. This report is also being submitted to the Secretary of Health and Mental Hygiene, the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

MEETINGS

During the year the Board held sixteen meetings, six of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for registration of pharmacists.

OFFICERS

Anthony Padussis was elected President and Paul Freiman was elected Secretary-Treasurer of the Board.

PERSONNEL

The staff consists of Roslyn Scheer, Executive Director; Dee Moore, Office Secretary and Patricia Cockrell, Steno-Clerk. After 5 years of service with the Board of Pharmacy, Margaret Lloyed resigned. Effective March 26, 1986, Peggie Lewis was employed to fill her position of Office Clerk II.

EXAMINATION

The Board conducted examinations for registration of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 25, 26, 27, 1985 and October 1, 2, and 3, 1985.

The applicants who were examined in June of 1985 were licensed in July, 1985 which is in F.Y. 1986. There were eighty-six applicants for the Board in June 1985. Eighty passed both the theoretical and practical portions of the examination and were registered. Six failed the examination.

Having previously passed the theoretical portion of the examination, one candidate took the practical examination in June. The candidate passed and was subsequently registered. Also, there was one reinstatement. Candidate took the Maryland Law only, passed and was reinstated.

There were twenty-three applicants for the Board in October 1985 (F.Y. 1986). Twenty passed both the theoretical and practical portions of the examination and were registered. Three failed the examination.

Data relative to the June 1986 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts consisting of the following:

Part I-NABPLEX

Part II consists of:
- Laboratory
- Maryland Law
- Federal Law

The NABPLEX and the Federal Law Exam are obtained from NABP. The Maryland Law Exam was compiled by members of the Board. The laboratory examination, requires the compounding of four prescriptions per applicant. The following table shows the number of pharmacists who were registered by examination during the past ten years.

Year	Number of Pharmacists
1976–1977	166
1977–1978	150
1978–1979	137
1979–1980	180
1980–1981	183
1981–1982	100
1982–1983	116
1983–1984	92
1984–1985	92
1985–1986	109

As in the past, many pharmacists applied for reciprocal registration in Maryland in order to accept positions with their employers who are opening stores in Maryland. Those applicants who did not meet our requirements concerning practical experience prior to or after registration in another state were advised that they must take our practical examination in order to verify their qualifications.

In all cases, an applicant for reciprocal registration must appear for a personal interview. The entire Board must act on whether or not to grant registration to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted registration by reciprocity and the number who were certified to register by reciprocity in other states during the past ten years.

Fiscal Year	Reciprocity	Certification
1976–1977	78	68
1977–1978	91	77
1978–1979	113	42
1979–1980	73	69
1980–1981	88	72
1981–1982	85	51
1982–1983	103	60

1983–1984	119	58
1984–1985	148	54
1985–1986	191	70
TOTAL	1,089	621

The table shows Maryland gained 468 pharmacists by reciprocity during the past ten years.

New permits to operate a pharmacy were issued to seventy-two (72) firms for the 1986 Fiscal Year.

PHARMACY PERMITS

Location	1985–1986
Counties:	
Anne Arundel	3
Baltimore	16
Frederick	5
Garrett	3
Harford	3
Howard	2
Kent	1
Montgomery	8
Prince Georges	4
Somerest	3
Wicomico	2
Wochester	4
Cecil	1
County Totals	55
Baltimore City	17
State-Wide Totals	72

MANUFACTURERS PERMITS

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics during 1986 were issued to four firms.

DANGEROUS DRUG DISTRIBUTORS PERMITS

The Board issued eleven (11) new permits to sell, distribute, give or in any way dispose of dangerous drugs during 1986.

OTHER PERMITS

The total number of pharmacies in the State of Maryland for 1986 fiscal year is 975 and the total number of pharmacists is 4,930 as of April 30, 1986.

LEGISLATION

The following legislation which effects the profession of pharmacy either directly or indirectly was enacted by the 1986 Maryland General Assembly. This list of Bills includes the purpose as it pertains to pharmacy.

SB 830 Drugs—Authorized Prescribers: Allows the boards that license physicians, dentists, and podiatrists to write rules and regulations to regulate dispensing by their licensees after consulting with the Board of Pharmacy. Also sets conditions that must be met in order for these licenses to dispense.

SB 831 Pharmacists—Pharmacist Rehabilitation Committee: Recognizes the existence of the Pharmacist Rehabilitation Committee and provides it with immunity from certain civil liability. Also protect certain records from discovery.

SB 944 State Ethics Commission—Penalties Appeals: Allows the State Ethics Commission to impose a civil penalty not to exceed $5,000 a day for each violation of Article 7.

HB 1475 Prescription Drug Abuse—Signature of Prescriber Required: Prohibits the use of a rubber stamp for prescriber's signature on a prescription.

HB 1476 Prescription Drug Abuse—Prescription Forms: Prohibits the use of a preprinted prescription form for a controlled substance.

HB 1479 Controlled Dangerous Substances—Schedule: Up-dates the list of controlled substances.

COOPERATIVE ACTIVITIES

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the University of Maryland—School of Pharmacy, the Maryland Administration, City, County and State Police and all Boards and Pharmacy Schools throughout the country.

DISCIPLINARY ACTIVITIES

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, State of Maryland Courts and other State Boards of Pharmacy. The wide range of complaints varied in severity. Listed below are statistics concerning the types of complaints for the period of April 1985 to April 1986.

miscellaneous*	47
mislabeled prescriptions	3
incorrect drug dispensed	14
generic substitution	1
wrong dosage dispensed	3
fraudulently obtains a license	2
intent to distribute CDS drugs illegally	3
shortages of controlled drugs	6
pharmacist abusing drugs	2
dispensing prescriptions without prescription	3
dispensing habits of pharmacist	6
TOTAL COMPLAINTS	90

* Complaints are on pricing, cleaniness, professionalism, dispensing physician and store hours.

Eleven pharmacists were charged with violation of the pharmacy laws. Three formal disciplinary hearings were held; eight cases were resolved by Consent Agreements. Five pharmacists' licenses were revoked. Six pharmacists' licenses were suspended, immediately stayed and the individuals placed on probation under certain conditions. Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations.

Is professionally, physically or mentally incompetent	9
Makes or files a false report or record	2
Fails to file or record any record required by law	3
Without a prescription dispenses any drug for which a prescription is required	8
Guilty of a felony	3
Provides professional services while using any controlled substance	5
Disciplined by a licensing or disciplinary authority of any other state	2
Fraudulently or deceptively obtains a license	1
Labeling requirement for prescription medicines	1

Two licenses which had been suspended, one reprimanded and two revoked in a prior year were reinstated.

FINANCES

All funds of the Board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

FINANCIAL STATEMENT

The Board of Pharmacy had revenues of $164,474 in 1984 and $172,053 in 1985. The Board of Pharmacy had expenditures of $120,632 in 1984 and $146,573 in 1985. The Board's budget is $143,530 for 1986 and $151,974 for 1987.

OTHER ACTIVITIES

In addition to the President, Anthony Padussis and Secretary-Treasurer, Paul Freiman, the Board consists of the following commissioners: Ralph Small, Steve Cohen, Leonard DeMino, Milton S. Moskowitz, Estelle Cohen, and William E. Adams. All the Commissioners are registered pharmacists in the State of Maryland with the exception of Ms. Cohen and Mr. Adams who are consumer (public) members of the Board.

REGULATIONS

The Board promulgated the following regulation:

1. Application Fee

At this time the Board is in the process of proposing for promulgation or amendment regulations concerning:

1. Parenteral/Sterile Enteral Compounding
2. Reporting Pharmacists' Addresses
3. Waiver of Full Service Requirement for Recognized Pharmaceutical Specialties
4. Prohibition Against Unprofessional Conduct

In 1986, the Board continued its excellent relationship with the Department of Health and Mental Hygiene. The cooperation and courtesy extended to the Board of Pharmacy by all members of the Department is appreciated by all the Board members.

Again the Board must commend our Executive Director, Roslyn Scheer, for her continued excellent management of the Board's business. Through her efforts the Board continues to operate smoothly and efficiently. In addition, the Secretary-Treasurer must commend our excellent secretaries Dee Moore and Pat Cockrell for their excellent work and cooperation. In addition, we welcome our newest secretary—Peggie Lewis.

This year marks the end of their term for two outstanding board members. Bernard Lachman has served as president for the last eight years. Through his efforts and leadership the Board of Pharmacy has grown and developed to its present statute—under President Lachman's leadership we have expanded our scope, developed our capabilities, and provided a leadership role in pharmacy so that our profession can better serve the citizens of our state. Estelle Cohen, the first consumer member on any of the Boards in the Department of Health and Mental Hygiene has served as the role model for public members now serving on all of the Boards and Commissions in Maryland. Through her efforts we have been able to meet the needs of the public in their concerns about the practice of pharmacy, and her development of the consumer role and function will serve as the standard for all future consumer members of this and other Boards. The Board of Pharmacy owes both of these departing members a lasting vote of gratitude. The Board of Pharmacy will sorely miss Dr. Lachman and Ms. Cohen and we wish them well in their future endeavors. We hope that we can continue to call on them, in the future, for their valued counsel and advice.

Respectfully submitted,

Paul Freiman
Secretary-Treasurer

MSHP ANNUAL REPORT

by
Moe Delcher, President

The Board of Directors, Officers, and membership of MSHP extend greeting at this Annual Meeting.

Monthly Meetings

Nine monthly meetings were held this year. Each meeting was hosted by the Pharmacy Department of a Baltimore Metropolitan institution. The Attendance at each meeting averages about 100 members.

Annual Seminar

Annual Seminar was held June 20 and 21st at the Carousel Hotel in Ocean City.

The 1987 Annual Seminar is scheduled for October in Williamsburg, Virginia.

Leadership Seminar

During July, MSHP in cooperation with the Virginia and District of Columbia Societies will be participating on an ASHP Leadership Seminar for officers, and committee chairpersons.

Strategic Planning

To adequately prepare for the future role of state societies, to set goals and objectives, a one day retreat is planned. Society leadership will focus on a variety of emergent trends and the potential influence on the society.

Dues

A general dues increase was instituted this year which affected active, associates, and student classifications.

Election Results

President—Roger Heer
Franklin Square

Board of Directors Member—Robert Feroli
John Hopkins

Treasurer—Kathleen Edwards
Good Samaritan

Secretary—Robert Katz
Washington County Hospital

Administration Office

Agreement was reached with MPhA on the lease of office space within the Kelly Building. This provides MSHP with a permanent mailing address and file repository. Further areas of cooperation are being investigated.

Peer Review Report

Over the past year, one complaint was submitted to Peer Review Committee for action. The letter received concerned a dispensing error. The pharmacy was contacted and a followup letter was sent to the patient.

Although the patient was concerned about the error, he was concerned that a person other than a pharmacist was actually filling the prescriptions. I feel this stemmed from the fact that the pharmacist did not deal with the situation when the error was reported.

There were no other issues referred to this committee.

Respectfully submitted,
Beverly Yachmetz, Chairman
Peer Review Committee

Continuing Education Coordinating Council
Annual Report

Officers for CECC this year were Rebecca Finley—MSHP, Chairman, Dave Banta—M.Ph.A., Secretary and Ilene Zuckerman—School of Pharmacy, Treasurer.

During the 1985–1986 year the CECC sponsored four continuing education programs. The first program of the year was held on October 3, 1985 and the topic was ostomy care. There were 45 attendees and three exhibitors and the evaluations were favorable.

The second program entitled "New Approaches to Infectious Diseases" was held on November 10, 1985. There were 100 attendees and evaluations were favorable.

The third program, "Update on Family Planning" was held on April 20, 1986 and there were 22 attendees. Once again evaluations were very favorable.

The final program of the year, The Role of the Pharmacist in Diabetic Patient Management was held on May 18, 1986 with 51 participants. This was a highly successful program which utilized a new format for the first time. Prior to the program registrants were distributed a self-instructional program to review prior to the seminar. The purpose of this was to assure a minimal level of knowledge of all participants. Both participants and faculty felt that this approach was advantageous.

Overall, this year programming was successful from a financial point of view as well, with income exceeding expenses for three of this year's four programs.

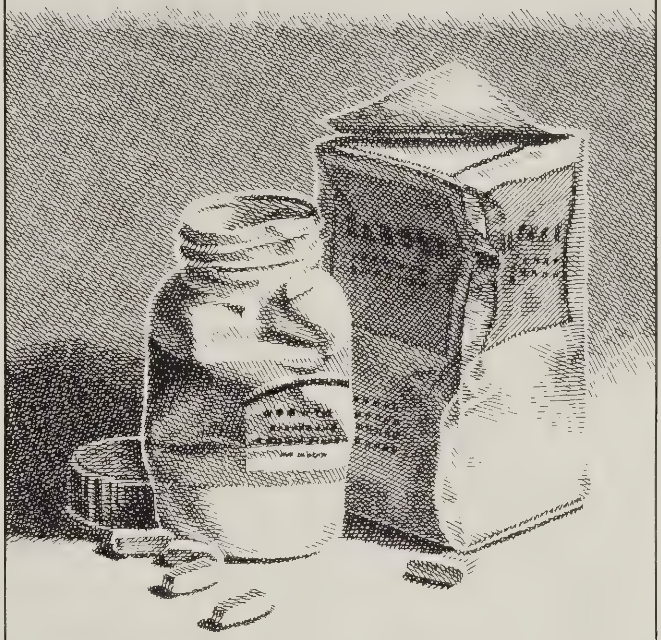
The subcommittee on planning for the 1986–87 year began meeting in February of 1986. Tentative programs for the upcoming year include Cancer—Early Detection and Prevention, September 1986; Airway Disease, November 1986; Arthritis, April 1986 and Cardiac Diseases, May 1987.

As of April 30, 1986 the bank balance for the CECC was $3,994.09.

Respectfully Submitted,
Rebecca S. Finley, Pharm.D., M.S.
Chairman 1985–86

Question #3

Your cost for dated and damaged goods?



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PHARMACISTS REHABILITATION COMMITTEE ANNUAL REPORT
MAY 28, 1986

HARRY FINKE AND TONY TOMMASELLO

I. INTRODUCTION

The Pharmacists Rehabilitation Committee was formed in response to a perceived need to establish a middle ground between pharmacist's dysfunction in practice and license suspension or revocation by the State Board. The Committee contracted its first treatment agreement in October 1983. The purpose of the Committee is to intervene and take appropriate action so that the impaired pharmacist can have a chance to address the dysfunction appropriately and save his/her career, mental and physical well being. The goal is to act as swiftly as possible to insure that the impaired pharmacist obtains proper counseling and medical treatment. Pharmacists who desire the aid of the Committee for rehabilitation must enter into a signed contract with the Committee. Information is maintained in complete confidence, protected by law, separate and apart from any Association or State Board records. Following a successful rehabilitation all records are purged from Committee files.

II. ACCOMPLISHMENTS

Senate bill 831 was passed and signed into law by Governor Hughes on May 27, 1986. The bill grants immunity from prosecution to Committee members and total privacy of our records. This establishes the confidentiality of the relationship between the Committee and the pharmacists it serves.

An event not reported in last year's report was the presentation of a pharmacy continuing education course entitled "Chemical Dependence Intervention" held on November 18, 1984. The program was designed to introduce pharmacists to the field of chemical dependence and the intervention strategies that work best. Approximately 60 pharmacists attended this course indicating the existence of a high degree of interest among pharmacy professionals. A repeat program in more depth seems appropriate to keep the profession current on new developments in this important area.

The Committee is participating with Med Chi and other professional associations in planning, structuring and coordinating an interdisciplinary conference on impaired professionals and the role of rehabilitation committees in their recovery.

The President and Chairman of the Pharmacists Rehabilitation Committee are attending the renowned University of Utah School on Alcoholism and Other Drug Dependencies, special section on Pharmacist intervention and rehabilitation. This is expected to improve the function of the Committee especially in areas of case management for the individual pharmacist and in resource development on a grand scale.

The Committee has influenced the School of Pharmacy in its decision to conduct a conference entitled "The Cocaine Epidemic: Implications for Professionals." One major piece of the conference will focus on modalities of treatment for health professionals with special emphasis on pharmacists.

The Committee has generated roughly $2,000 over the last three years in the form of contributions from McNeil and Sandoz drug companies, the Maryland Society of Hospital Pharmacists, and of course the Maryland Pharmacists Association. We especially thank all the association members who contributed to the voluntary fund. The Committee also recognizes the support of the University of Maryland School of Pharmacy which provides office space and support services that enable the Committee to function.

III. TREATMENT REPORT

Since its inception, the Committee has officially contacted 29 pharmacists of whom all but 4 signed contracts for treatment. Of the 25 who agreed to participate in treatment 15 currently remain in treatment and in active recovery, 8 have successfully completed 2 years of treatment and 2 are considered treatment failures. Thus 23 pharmacy careers have been revitalized through the cooperative effort between the pharmacist and the Committee.

IV. LIMITATIONS AND NEEDS

The Committee suffers geographical and financial limitations. Geographically the Committee is centered in Baltimore City and experiences difficulty in sustaining a viable link with pharmacists distant from the city. We would especially like to establish outreach services for pharmacists in Western and Southern Maryland and on the Eastern Shore. This effort obviously entails the need for an expansion of the Committee staff on both a voluntary and renumeration basis. The investment of additional support in dollars and manpower will pay large dividends in the form of greater service to the pharmacy community.

Financial concerns are thus of major importance. The committee has decided to employ a program coordinator two days a month for as long as our meager budget can sustain the position. Funding must be increased if the Committee is to broaden its service base or indeed to continue adequate service to the current caseload. Plans to increase funding include overtures to drug companies for annual grants and local efforts to raise funds through donations at local conventions. There is no doubt that in order for the Committee to maintain continuity we must have assurance of sufficient fiduciary support.

Although money is an important consideration it is but one element of a successful program. The Committee encourages the pharmacy community to demonstrate its support of this most important work by opening up employment opportunities for pharmacists in recovery. The record shows that pharmacists can return to active employment once their recovery is successfully underway.

V. SUMMARY

In conclusion, the success of the pharmacists who have participated in the Committee intervention process demonstrates their ability to continue in a viable career and should provide an infusion of optimism regarding the recovery potential of properly treated chemical dependence.

The committee recognizes the volunteer time and effort of the following committee members:

Gil Cohen
Steve Cohen
John Davis
Geri Epley
Harry Finke
Doug Haggerty
Bernard Lachman
Mary Sue Long
Barry Means
Robert Patty
Tony Tommasello

Will We or Won't We?

We will increase enrollment in our baccalaureate program. While we had enlarged the size of the entering class from 80 to 90 two years ago, the serious shortage of pharmacists has caused us to admit 100 students this coming Fall. We are fortunate that there has been a 20% increase in applications compared to last year. This will allow us to continue to be selective in our admissions process, even with the larger class.

We will improve our graduaate studies and research programs. Our research programs continue to grow, especially since the move into our new building. The new space and the considerable amount of scientific equipment added through major funding from the State of Maryland have given the faculty the kind of research support base that stimulates our research priorities so that we can apply additional resources in the most effective manner.

The graduate programs are being examined in view of the major conceptual changes that are occurring in research. It has been pointed out by others that physics was the dominant research discipline during the earlier part of this century, but that molecular biology has now taken over and will continue to dominate for years to come. The concept of molecular biology, biotechnology, or biomolecular engineering now runs throughout the biological and chemical sciences, and therefore impacts on all our basic science research disciplines in pharmacy. It has become paramount that those students completing graduate programs in pharmacology, pharmaceutics and medicinal chemistry/pharmacognosy have an adequate educational and research exposure in the field of molecular biology so that they can not only use the techniques as research tools, but also be able to conduct basic research in the field as it relates to their own discipline.

Will we or won't we move to an all Pharm.D. program. We've started the process to collect enough information to make that decision later this Fall. A number of individuals have said to me that they've heard that the decision has already been made to move to the all Pharm.D. program. That's not correct! We've got to collect a lot of information and opinions before the faculty can vote on the matter. The need for the program, the manpower situation in the State, the impact on past graduates, and the cost (can we afford it?) are just some of the factors that we must consider. We are going to listen to all interested parties and hope that our planning effort will be so structured that both sides of the debate will be clearly heard.

William J. Kinnard, Jr., Ph.D
DEAN

104TH Annual Convention
MARYLAND PHARMACEUTICAL ASSOCIATION
MEMBERSHIP COMPARISON REPORT
1986

June 86

	1983	1984	1985	1986
TOTAL MEMBERS TO DATE:	938	1007	1023	1044
NEW MEMBERS TO DATE:	104	96	79	67

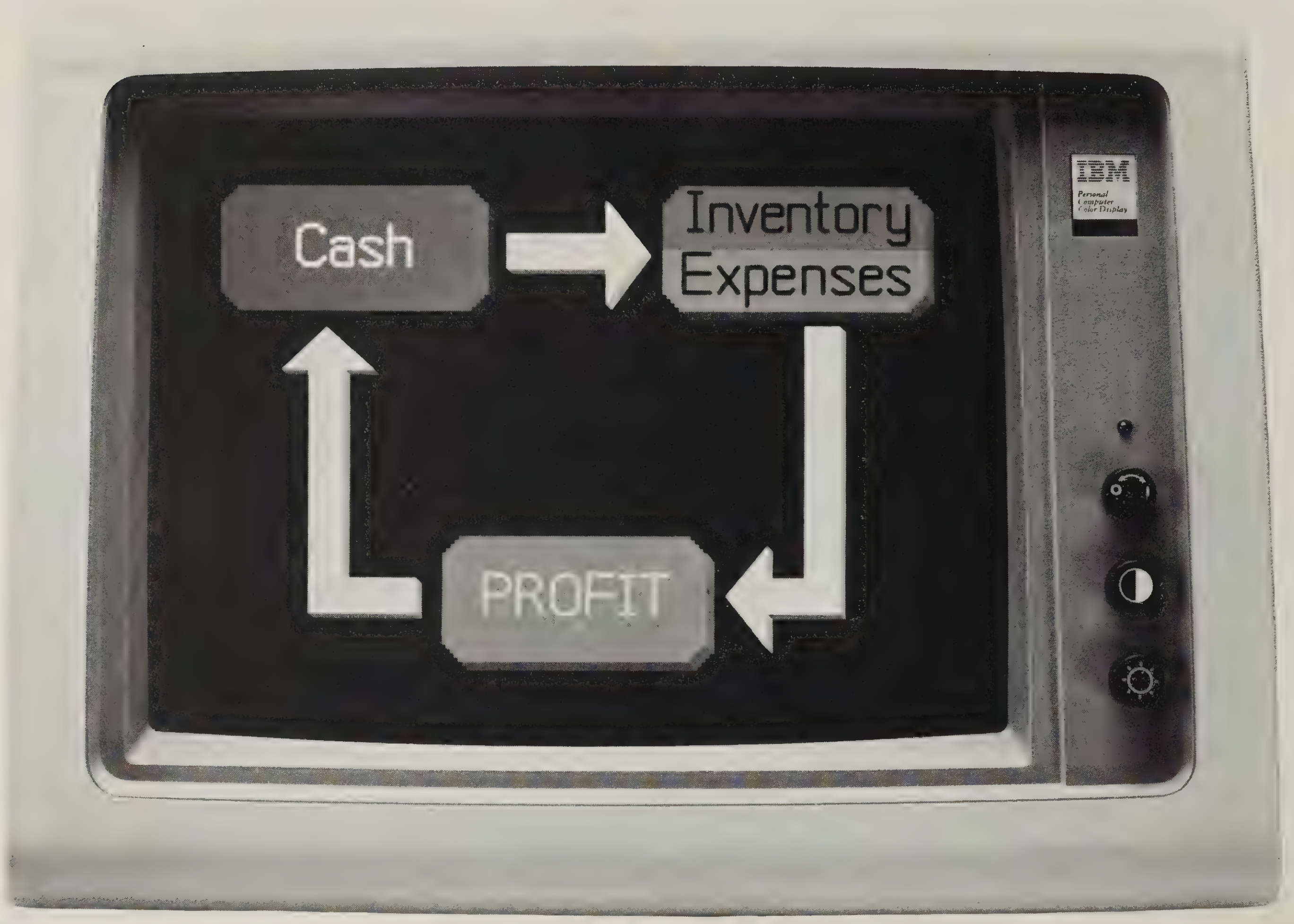
COMPARISON: 1985 TO 1986	
MEMBERS TO DATE:	+21
New Members to date:	−12

	1983	1984	1985	1986	COMPARISON 85–86
BREAKDOWN:					
OWNER-MANAGER	185	193	210	186	−24
NON-OWNER	422	451	451	515	+64
PLEDGE—1ST YEAR	56	61	52	45	−7
2ND YEAR	32	30	40	34	−6
HOSPITAL	33	27	33	24	−9
GRADUATE	2	6	9	3	−6
RETIRED	89	116	113	120	+7
NON-RESIDENT	80	85	82	70	−12
JOINT	7	7	7	6	−1
ASSOCIATE	32	31	29	41	+11
Comparison:	938	1007	1023	1044	+21

The statistics show that we are making steady progress in membership when compared to previous years. I would like to extend my fullest appreciation to the Membership Committee, David Banta, and Beverly Litsinger for their time and efforts this year.

Madeline Feinberg
Chairperson

Follow the arrows to better cash flow management.



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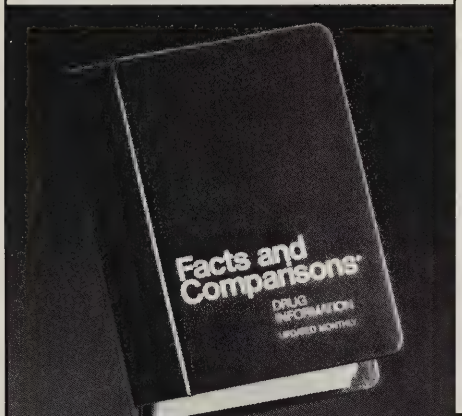

Facts and Comparisons lists more than 10,000 drugs, including over 3,000 OTC items. Group monographs are given for closely related drugs; plus actions, indications, and contraindications; warnings and precautions, interactions between drugs, adverse reactions; administration, dosage, overdosage, and patient instructions.

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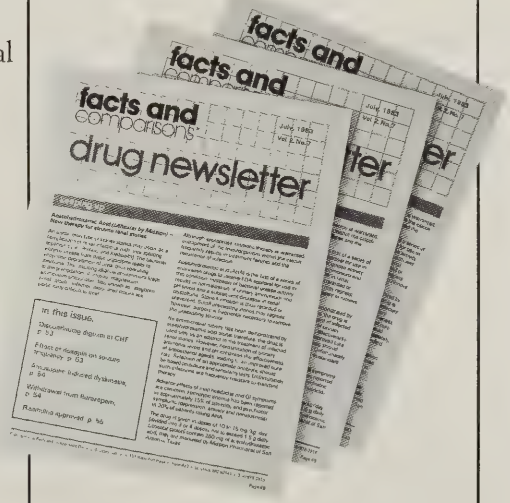

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"TIMELY TOPICS"

A regular monthly feature sponsored by the Parke-Davis Center for the Education of the Elderly and the Elder-Health Program, University of Maryland School of Pharmacy. At the conclusion of each series, a sample "Elder-Ed Talk" for presentation to community groups will be outlined.

Cancer, Nutrition, and the Elderly: A Closer Look at Some of the Facts. Part II.

by
Peter P. Lamy, Ph.D.
Madeline Feinberg, PharmBS

Caloric Intake and Fat

A number of animal experiments showed that nutritional restrictions, early in life, delay onset of chronic diseases and cancer, and extend life span. This was summarized by the statement that reduced caloric intake will decrease development of spontaneous tumors and inhibit their growth. As previously noted, the National Cancer Institute counsels reduced fat intake. This has been said to be "very naive and much too simple." Fat intake, per se, may not be the risk factor. Energy balance is required. Pariza states that obesity and caloric intake have been linked to carcinogenesis, not fat.

Nevertheless, the food industry has responded with gusto. One chicken wholesaler now advertises the "chicken without a pot." These chickens, it has also been claimed, have 13% fat as opposed to others with 16% fat. The savings would be less than 2 g fat per 4 oz to 6 oz serving, enough for some, not enough for others.

Fiber

The evidence for a beneficial effect of fiber against colon cancer is as strong as it can be without clinical trials. Burkit first suggested that fiber might be helpful in various instances, such as diabetes, heart disease, and cancer. Fiber, Burkit has proposed, increases the amount of feces passed, thereby reducing the carcinogenic substances in the bowel. Fiber also alters transit time, reducing contact between carcinogen and colon. It also alters the bacterial metabolism. The mode of action of fiber than would be a) binding of carcinogens and cancer promoters, and b) lowering of bowel pH, thereby inhibiting the action of carcinogens.

However, opposing voices have been heard. Man, it is claimed, was not made for a diet of high fiber and meatless meals. More importantly, there ought to be a differentiation between fibers. Soluble fiber (oat and corn bran, psyllium hydrocolloid) indeed stimulates cell proliferation and increases the number of colonic tumors. Furthermore, dietary bran can significantly influence the availability of calcium (lack of which is thought to be an important risk factor in colorectal cancer), copper, magnesium, manganese, and zinc.

Cancer and Malnutrition

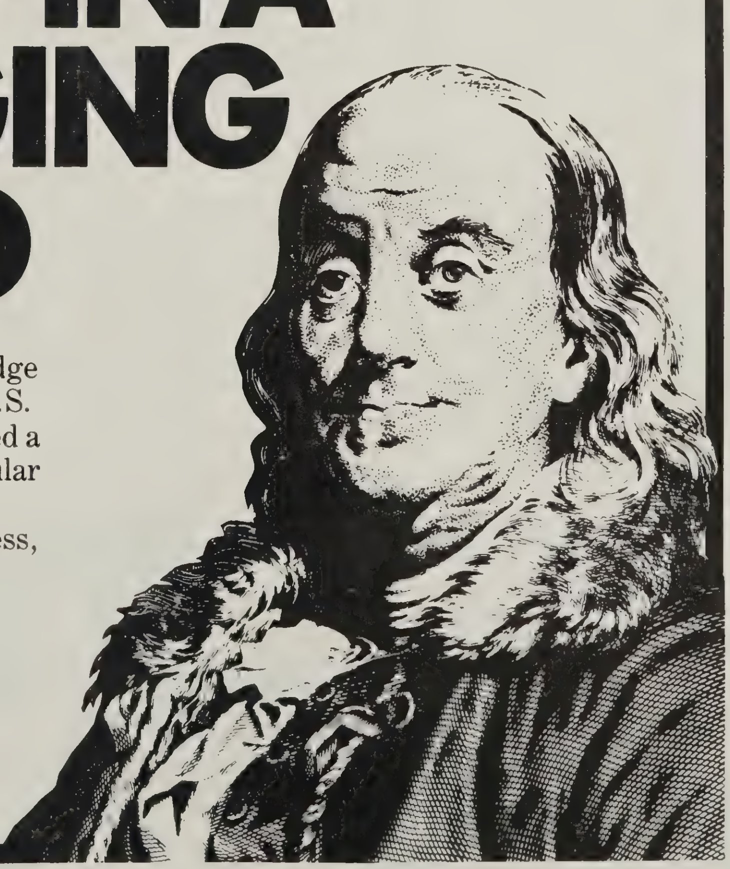
Of all patients, elderly are most likely most at risk, because of their decreased ability to synthesize protein and increasing protein catabolism. Cachexia is a severe form of protein calorie malnutrition, which is common in advanced cancer. There are two main causes of PCM: a) decreased food intake and b) metabolic abnormalities due to the tumor. For example, head and neck cancer can cause swallowing difficulties, GI cancer can cause dysphagia, obstruction, and malabsorption, and cancer treatment itself can alter the structure and function of the GI tract. There is another reason for malnutrition in cancer patients. Most of these patients present with hypoalbuminemia, possibly due to protein catabolism, triggered by interleukin-1, which is produced as long as the tumor exists. The tumor, in fact, acts as a nitrogen trap or energy sink.

Nevertheless, nutritional support is indicated, since a good nutritional status is often associated with a recovery of immunocompetence and prolonged survival. Involuntary weight loss equal to or greater than six percent of original body weight is a strong indication for action which, initially, should involve supervision of a patient's food intake, use of antiemetic drugs, enteral supplements if necessary, and psychologic treatment, if necessary.

Total parenteral nutrition is often the last attempt to restore the patient's nutritional status. However, it may be ineffective and may be contraindicated, since it may stimulate cachexia. Absence of response to aggressive nutritional support is usually ascribed to the tumor. Interleukin-1 and other factors may produce insulin resistance and block entry of sugar into muscle. Furthermore, nutritional support may enhance cell proliferation and, thus, enhance tumor growth. It might also be argued that malnutrition is lethal. To solve these dilemmas, it has been suggested that total parenteral nutrition be used for any patient where cancer chemotherapy may promise a good clinical outcome. A somewhat better result with TPNs may be obtained when the branched-chain amino acids are used, i.e., leucine, isoleucine, and valine. These can possibly spare muscle tissue from interleukin-1 induced muscle protein breakdown. They may also heighten responsiveness to chemotherapy or irradiation, and minimize toxicity of chemotherapeutic agents. Other new supplements that may prove helpful are the synthetic fats or medium- and long-chain fatty acids, which are thought to improve lipid penetration into the muscle. Xylitol, which enhances fat metabolism, may also be of value.

* * * *

The last article in the series will deal with specific cancers and risk factors. An outline for a community program, geared to the older audience will be given.



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PHARMACY IN LONG-TERM CARE

by
Peter P. Lamy, PhD

Introduction: The National Institute on Aging has called for the development of a community-based chronic care network which, in its opinion, can only be effective if it is based on a multidisciplinary effort. Clearly, Pharmacy has a major role in that developing network. The Office of Technology Assessment, in its report ''Technology and Aging'', has stated that ''drugs are probably the most cost-effective modality of chronic disease management''. Indeed, more than two-thirds of all prescriptions dispensed are for chronic care.

The Current Chronic Care System and Pharmacy: Approximately five percent of the elderly are residents of nursing homes. In 1974, pharmacists were mandated by the federal government to review the therapeutic regimen of all SNF patients at least monthly. In a Report to Congress (June 25, 1980), the Comptroller General recognized this activity as both economically and clinically effective. Indeed, in ICF-MR institutions, either pharmacists or nurses must review patient medication regimens, but if the review is performed by a nurse, a pharmacist must validate it. Similar safeguards have not been developed for community-living elderly. Perhaps because of this lack, between 15 and 25% of elderly are admitted to acute care hospitals because of adverse drug reactions. British data indicate that 40% of community-living elderly suffer from adverse drug reactions, and, according to the Royal College of Physicians, one of the three major reasons for adverse drug reactions in the elderly is inadequate supervision of long-term care drugs. Furthermore, according to data developed by the AARP, 20% of the elderly do not have all prescriptions filled that they receive and 44% of elderly stop their chronic care medication within the first year of starting it, either because of cost or, more likely, because of adverse effects that they cannot or will not tolerate. A hospital-based study in England suggest that about 85% of all adverse drug reactions and interactions in the elderly could have been avoided if the correct drug had been chosen.

Changes and Alternate Care Modalities

Changing demographics, cost containment needs, quality-of-life issues and quality-of-care issues are bringing about major changes in the traditional approach to long term care.

Changing Demographics: Dramatic demographic changes are taking place. The number of people 65 years old and over is increasing sharply in the United States, both proportionally (due to a decreasing birthrate) and numerically (due to increasing life expectancy). Most importantly, the aging population, itself, is aging. Those 85 years old and over have increased by 140% over the last decade, and will again double in the near future. In fact, among those 85 years old and over, those 95 years old and over are the fastest-growing segment in our population.

Changing Health Care Status: Currently, there are approximately 4.6 million persons 65 years old and over who suffer from limitations of activities of daily living (ADL) or instrumental activities of daily living (IADL, cognitive impairment). Under a projected ''best care'' scenario, this number may double by the year 2000, but under a ''worst case'' scenario, it may quadruple. This should not be surprising, as these projections parallel those for the increasingly aging population. Chronic disabilities occur in 15% of the total population, but in 66% of those 85 years old and over. In fact, for every elderly nursing home resident, there is already one, or possibly two, elderly of equally poor health status living in the community. A 68 year old female living today has a life expectancy of another 20 years. Almost half of these years will be spent in progressive incapacity. It is noteworthy that among the 10 leading causes of dependency, visual, hearing and speech impairments rank high, making effective communications with these persons very difficult.

Changing Care Environment: Approximately five percent of elderly patients are being cared for in nursing homes, occupying about 1.3 million beds. By the year 2000, 2.8 million nursing home beds would be needed to accommodate five percent of the elderly, an unattainable goal. More, older, and more seriously ill elderly will need to be cared for at home.

This trend is reinforced by changes occurring acute care hospitals. DRG-mandated changes are causing the closing of many beds. Among small rural hospitals (50

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TABLE 1
The Home Care Patient

Classification by:
1. Diagnostic category (medical model)
2. Sociodemographic characteristics with restrictions in
    - —ADLs
    - —IADLS
3. Type of care
    - —immediately following deinstitutionalization
    - —acute
    - —chronic, long-term care
    - —terminal care
4. Need to prevent institutionalization

beds or less), nearly 400 are already approved to provide "swing" bed care, i.e., they may use beds for chronic or acute care, depending on need. The impact of the impending resource utilization groups (RUGs) on the institutional system has yet to be evaluated. Currently, 38% of all acute care hospital inpatient days are attributed to those 65 years old and over. Hospital inpatients days will rise from approximately 265 million in 1980 to 305 million in 1990, with 90% of the increase due to the older population. Clearly, this segment of acute hospital care will be a major target for more cost-containment measures.

The outcome of these changes individually and combined, will be a fast-developing home care segment. In 1966, there were 993 medicare home health agencies, but in 1984, there were 5071.

The Home Care Environment: Subacute, heavy care is on the increase, providing skilled nursing care for people discharged from hospitals. But, as Table I shows, there are quite a number of different home care patients, each needing individual care offered according to an individually developed care plan. Thirty percent of unattached older males and 50% of unattached older females already live with their families, who act as caregivers. As the population ages, more and more females will seek help of this nature. Help, it is hoped, will be given by caregivers. Among those 55 to 64 years old (more than 22 million), many are females, and many are caregivers. Thus, the health, social, and economic problems of the elderly, particularly of those over 70 years, are mainly problems of women (women outnumber men in a ratio of 3:1 in that age group). Women are also more sensitive to adverse drug reactions than men. Caregivers, too, need help. They need help in understanding the drug regimens prescribed for their older relatives, they need help in learning how to observe drug effects and report them to a primary provider (the aide-therapist concept) for adjustment of the regimen, and they need help for themselves. It has been estimated that approximately 50% of these caregivers suffer from mental and physical exhaustion and are being maintained with medications.

Close supervision of drug use and drug effects is of particular importance in this relatively unstructured environment. Two factors mandate that close supervision: first, there are still no guidelines on the use of drugs for elderly, particularly chronic care patients. Secondly, all compliance strategies, developed for the acute care sector, have been shown to be less effective in the chronic care sector, and the involvement of the caregiver and family is most necessary to achieve better adherence to an agreed-upon regimen. All of these considerations, of course, also apply to elderly in domiciliary care, congregate housing, or sheltered housing.

Pharmacy Services in the Chronic Care Sector: The need for pharmacy services in the chronic care sector has been documented. It does not end with the dispensing of a prescription, but starts there, based on the effective models developed and proved in other sectors of chronic health care. It may involve assistance in selection of an "alternate" drug which may cause fewer or more tolerable side effects, the development of an "at risk" patient medication record, or a host of other services, as outlined in Table II. Major considerations concerning the patient and the drug need to be addressed before and after a prescription is filled and dispensed (Tables III and IV). Based on services in skilled nursing facilities and ICF-MR institutions, pharmacy needs to deliver the same kind of services, possibly even expanded, to the home care patient, who is most

TABLE 2
Pharmacy in Long-Term Care*

Home Care, Level I	*Pharmacist's Services*
Well, ambulatory elderly	Drugs, education, monitoring, preventive care, nutritional advice, referrals, consumer education. Provision of special packaging for medications.
Housebound with activity limitations, but relatively well	More intensive monitoring, chart review, special education, family counseling, follow-up. "At Risk" Patient Medication Record.
Level II	
Ambulatory, chronic care with multiple diseases and disabilities	Home health care provision of IV, TPN, enteral therapy, oxygen, DME
Level III	
Day Care Center patients	Coordinate ancillary home care (housekeeping, nursing, PT, etc)
Level IV	
Homebound, dependent	Consistent monitoring, counseling and follow-up to patient, family, physician and other providers.

Adapted from: Lamy, P. P.: Am. J. Pharm. Edu., 45:391, 1981
* Services for each level of care are build on services offered in the less serious level of care.

TABLE 3
Chronic Care Drug Use: Patient Considerations

1. Is drug or non-drug therapy better for patient?
2. Is patient impaired mentally, physically, financially? Can patient read, speak and understand english?
3. Is patient's sensorium impaired?
4. Can patient manage drug administration and tolerate possible drug side effects?
5. Can patient administer dosage form selected?
6. Does patient live alone?
7. How many physicians does patient consult?

TABLE 4
Chronic Care Drug Use: Drug Considerations

1. Is drug necessary? What dose? Which dosage form?
2. What are drug's anticipated
   a. therapeutic benefits?
   b. side effects?
3. Will drug interfere with intercurrent diseases? Existing drug regimen?
4. Can possible adverse effects cumulate with similar effects of existing regimen?
5. Is drug affordable?
6. Can drug be self-administered?
7. Can drug be stopped? When?

often afflicted with multiple diseases, being maintained with multiple drugs. Pharmacy services will help to prevent and/or minimize adverse effects which can impact on a patient's quality of life, and the mental, physical, and nutritional status of a chronic-care patient. Much of non-institutional chronic care drug use is self-care, and pharmacists must help to improve provider-assisted long-term self-care (Table V).

TABLE 5
Improving Provider-Assisted Long-Term Self-Care

1. Establish partnership-like relation and trust
2. Direct efforts toward enabling factors and good information base.
3. Use Cues
   a. Tailor drug administration to activities of daily living
4. Use reminders
   a. Stress importance of medically-assisted self-care at every visit
5. Follow-up
   a. Call if appointment or drug refill is missed
   b. Vary number of contacts directly with degree of cooperation
   c. Stress need for feedback
6. Use rewards
   a. Recognize patient effort, progress
7. Achieve social support
   a. Involve family caregiver

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Dear Dave:

Recently, I gave an elder-ed talk to a group of senior citizens. It was really just an extension of the patient counseling I do in the store every day. The format was made easier by the elder-ed lectures which have been appearing in the Maryland Pharmacist. The handouts and medication cards which I received from the elder-ed office completed and complemented the presentation. The combined success of my in-store patient counseling and the elder-ed talks have contributed greatly to my remaining satisfied with chain pharmacy practice. I would encourage my fellow chain pharmacists to consider incorporating these practices into their regular work schedule.

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Ask your health care professionals these questions about your prescription medicines.

1. What is the name of the drug and what is it supposed to do?
2. How and when do I take it – and for how long?
3. What foods, drinks, other medicines, or activities should I avoid while taking this drug?
4. Are there any side effects, and what do I do if they occur?
5. Is there any written information available about the drug?

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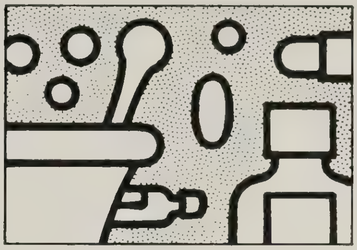

October Is Immunization Month

Prevention is the Best Health Insurance!

Childhood diseases — diphtheria, tetanus (lockjaw), pertussis (whooping cough), polio, measles (rubeola), rubella (German measles) and mumps. The first two years of your child's life are critical. You can provide the protection your baby needs through the proper immunizations. All children should be immunized early in life so that they require only stimulating or booster doses prior to entering school.

Immunity against these diseases is often required for entrance into any public, private or parochial elementary school, day care center or nursery school.

Recommended Immunization Schedule
for Normal Children Starting in Infancy

Age	*Immunizations Needed*
2 - 4 months	DTP (diphtheria, tetanus and pertussis) TOPV (trivalent oral polio vaccine)
4 - 6 months	DTP and TOPV
6 - 8 months	DTP
8 - 11 months	Tuberculin Skin Test
15 months	Measles, Mumps and Rubella
1½ years	DTP and TOPV
4 - 6 years (school enterers)	DTP and TOPV
Every 10 years thereafter	TD (adult tetanus-diphtheria)

Recommended Immunization Schedule
Starting Age 14 Months Through 5 Years

Visit	*Immunizations Needed*
First	DTP (diphtheria, tetanus, pertussis) TOPV (trivalent oral polio) Tuberculin skin test
1 month later	Measles, Mumps, Rubella
2 months later	DTP and TOPV
4 months later	DTP
6 - 12 months later or preschool	*DTP and TOPV
Age 14 - 16 years	Td (adult tetanus-diphtheria) and every 10 years thereafter

*Td, not DTP, is given to children over 6 years of age.

Recommended Immunization Schedule
Starting at 6 Years of Age and Older

Visit	*Immunizations Needed*
First	Td (adult tetanus-diphtheria) TOPV (trivalent oral polio) Tuberculin skin test
1 month later	Measles, Mumps, Rubella
2 months later	Td and TOPV
6 - 12 months later	Td and TOPV
Age 14 - 16 years	Td and every 10 years thereafter

Any interruption in an immunization series does not necessitate starting these series over again.

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NURSE PRACTITIONERS
Who We Are and How We Function in the Health Care System

by Linda Foster
Senior Nurse Practitioner
Johns Hopkins Health Plan

The Department of Health and Mental Hygiene recently sent to all licensed pharmacists in the State of Maryland an announcement stating that prescriptions properly issued by nurse practitioners may now be filled. Please refer to the information sent to you for the specifics in prescribing. This announcement was made after the Maryland Attorney Generals' office issues a formal opinion concluding that pharmacists are not prohibited by Maryland law from filling prescriptions written by nurse practitioners.

For pharmacists who have not had experience working with the almost 500 nurse practitioners in Maryland, here are a few facts and some historical data.

Nurse practitioners are registered nurses who have completed certificate or masters programs in a special area of health care. They are providing comprehensive health care to people of all ages in collaboration with other health care providers. The areas of specialization include neonatal care, pediatrics, adult, family, school, obstetric, gynecologic, and gerontology. In order to practice in the State of Maryland, a nurse practitioner must be licensed as a Registered Nurse, have completed a nurse practitioner program approved by the Board of Nursing, have successfully completed a national certifying exam acceptable to the Board, and have a written agreement with a physician or physician group that has been approved by a joint committee composed of physicians and nurse practitioners. Recertification is required every five years, and includes: completion of continuing education requirements; and re-evaluation of the practice setting, written agreements, and credentials.

The nurse practitioner and physician collaboration began in Colorado in the early 1960's. Loretta Ford, a nurse, and Henry K. Silver, a physician, established the first nurse practitioner program in maternal child health. This program started in response to a shortage of physician in some geographical areas. Silver and Ford believed that use of nurse practitioners in primary care would provide to patients more comprehensive and effective services, especially in the areas of prevention, health maintenance, mental health, chronic illness management, and health education. Physicians teamed with nurse practitioners could devote more time to managing complex and difficult health problems, thereby maintaining higher levels of competence in diagnosis and therapy. Practices appropriately utilizing nurse practitioners have found them to be cost effective and to increase the productivity of the practices. (1–6)

Educational requirements for nurse practitioners are changing. By 1990, all nurse practitioners will be required to have Masters Degrees. Nurse practitioners in Maryland are graduates of either a continuing education program or a Masters Program, and the majority are graduates from programs at the University of Maryland. Both programs include extensive courses in physical assessment, diagnosis and management, teaching and counseling, and pharmacology. These programs also include clinical practice with physicians and pharmacists in varied health care settings. We are very fortunate to have the School of Pharmacy at the University of Maryland. The faculty has contributed to development of the nurse practitioner curriculum, and with faculty from the Johns Hopkins University, provide the formal instruction in pharmacology.

Nurse practitioners are currently practicing in hospitals, ambulatory clinics, HMO's, emergency rooms, schools, nursing homes, senior citizen centers, private practices, universities and many other facilities. Services performed by the nurse practitioner include complete physical examinations, health assessments, treatment of common acute illnesses, treatment of chronic stable medical conditions, and health counseling. The major focus of the nurse practitioner is prevention through education, teaching people how to stay well and how to prevent illness from recurring. (7–10)

As members of the health care team, we are practicing in collaboration with physicians, pharmacists, and other health care providers to give the best of health care to our clients. As a team, we can improve the quality of health care provided to the citizens of Maryland.

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1986 Lilly Digest

This preliminary *Lilly Digest* report shows that total sales during 1985 increased more than 3% over the prior year but net profit failed to keep pace and declined. Prescription revenue accounted for the overall sales increase, as other sales were down, even though fewer prescriptions were dispensed. Further comparison shows . . .

Total sales established a record high of over $589,000, up more than 3% from the 1984 figure. This is lower than the average annual growth rate of 9% observed over the decade. Interestingly, the average growth rate since 1980 appears to have stabilized in the range of 5 to 6%. Prescription sales rose over 6% and substantially outpaced other sales, which fell 1.6%. Prescription income accounts for more than 66 cents of every revenue dollar.

Gross margin in dollars increased almost 2% but declined to 32.6% as a percent of sales. Total expenses fell to a record low of 29.8% of total revenue. This reduction was the result of a decline in employees' wages, which more than offset an increase in proprietor's salary and in miscellaneous operating costs. The combined effect of these changes was that net profit before taxes fell 7.5% to equal 2.8% of total sales.

Although total expenses declined percentagewise, they increased dollarwise (up about $4,500, or 2.6%, from the previous year). Average proprietor's or manager's salary rose both in dollars (up $1,553) and as a percent of sales (up to 5.9%). Employees' wages declined in dollars and as a percent—down over $500 to 10.1% of sales. Rent advanced almost 6% in dollars but remained unchanged as a percent of sales at 2.4%. Miscellaneous operating costs increased by about $2,700, a 4.2% increase over the previous year's figure. In addition, these costs took up a larger share of the sales dollar—up from 11.2% to 11.4% of total revenue.

Net profit before taxes dropped over 7%, down $1,217 from the 1984 figure. Total income (proprietor's salary plus net profit before taxes) advanced to just over $51,000, a 0.7% rise, but declined as a percentage to 8.7% of sales.

Prescription inventory required a somewhat larger dollar investment (up over $2,400) and increased from 10.5% to 10.6% of prescription income. However, general merchandise inventory required fewer dollars (down almost $500) but rose to 21.9% of general stock sales. The prescription department's sales productivity stayed about the same at $9.47 per stock dollar as compared with $9.50 recorded for 1984. Other merchandise sales productivity also was relatively unchanged at $4.57.

New prescriptions rose as a percent of total prescriptions to 49.5%, but the number of prescriptions dispensed fell slightly as compared with similar figures for 1984. On the average, there were fewer renewed prescriptions dispensed during 1985—down over 4% from last year. These changes resulted in a 2.4% decline in total prescriptions dispensed. The average prescription charge advanced 8.8% to $13.05 during 1985, an increase of $1.05 over the 1984 figure of $12.00.

The size of the average *Lilly Digest* pharmacy increased 7.4% to over 2,600 square feet during 1985. Sales productivity per square foot of selling space dropped about $7 (down to $222.14) from the earlier year's figure—a 3.3% decline. At 61 hours per week, the typical *Digest* pharmacy was open one hour less during 1985.

The following table summarizes the operating figures of 1,224 independent community pharmacies and compares these with the 1985 *Lilly Digest* database of 1,341 stores. The completed edition of the *Lilly Digest* will be distributed during the fall of this year.

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Averages per Pharmacy	1985 (Preliminary Sample) (1,224 Pharmacies)	1984 (Full Sample) (1,341 Pharmacies)	Amount/ Percent of Change
Sales			
Prescription	$ 366,903— 62.3%	$ 345,435— 60.5%	+$21,468— 6.2%
Other	222,439— 37.7%	225,878— 39.5%	−$ 3,439— 1.6%
Total	$ 589,342—100.0%	$ 571,313—100.0%	+$18,029— 3.2%
Cost of goods sold	397,508— 67.4%	382,757— 67.0%	+$14,751— 3.9%
Gross margin	$ 191,834— 32.6%	$ 188,556— 33.0%	+$ 3,278— 1.7%
Expenses			
Proprietor's or manager's salary	$ 34,854— 5.9%	$ 33,301— 5.8%	+$ 1,553— 4.7%
Employees' wages	59,598— 10.1%	60,126— 10.5%	−$ 528— 0.9%
Rent	14,208— 2.4%	13,428— 2.4%	+$ 780— 5.8%
Miscellaneous operating costs	67,016— 11.4%	64,326— 11.2%	+$ 2,690— 4.2%
Total expenses	$ 175,676— 29.8%	$ 171,181— 29.9%	+$ 4,495— 2.6%
Net profit (before taxes)	$ 16,158— 2.8%	$ 17,375— 3.1%	−$ 1,217— 7.5%
Total income	$ 51,012— 8.7%	$ 50,676— 8.9%	+$ 336— 0.7%
Value of inventory at cost and as a percent of sales			
Prescription	$ 38,753— 10.6%	$ 36,343— 10.5%	+$ 2,410— 6.6%
Other	48,625— 21.9%	49,115— 21.7%	−$ 490— 1.0%
Total	$ 87,378— 14.8%	$ 85,458— 15.0%	+$ 1,920— 2.3%
Annual inventory turnover rate	4.5 times	4.6 times	
Prescriptions dispensed			
New	13,919— 49.5%	13,975— 48.6%	− 56— 0.4%
Renewed	14,198— 50.5%	14,801— 51.4%	− 603— 4.3%
Total	28,117—100.0%	28,776—100.0%	− 659— 2.4%
Average prescription charge	$ 13.05	$ 12.00	+$ 1.05— 8.8%
Floor area*	2,653 sq ft	2,471 sq ft	+ 182— 7.4%
Sales per square foot*	$222.14	$229.36	−$ 7.22— 3.3%
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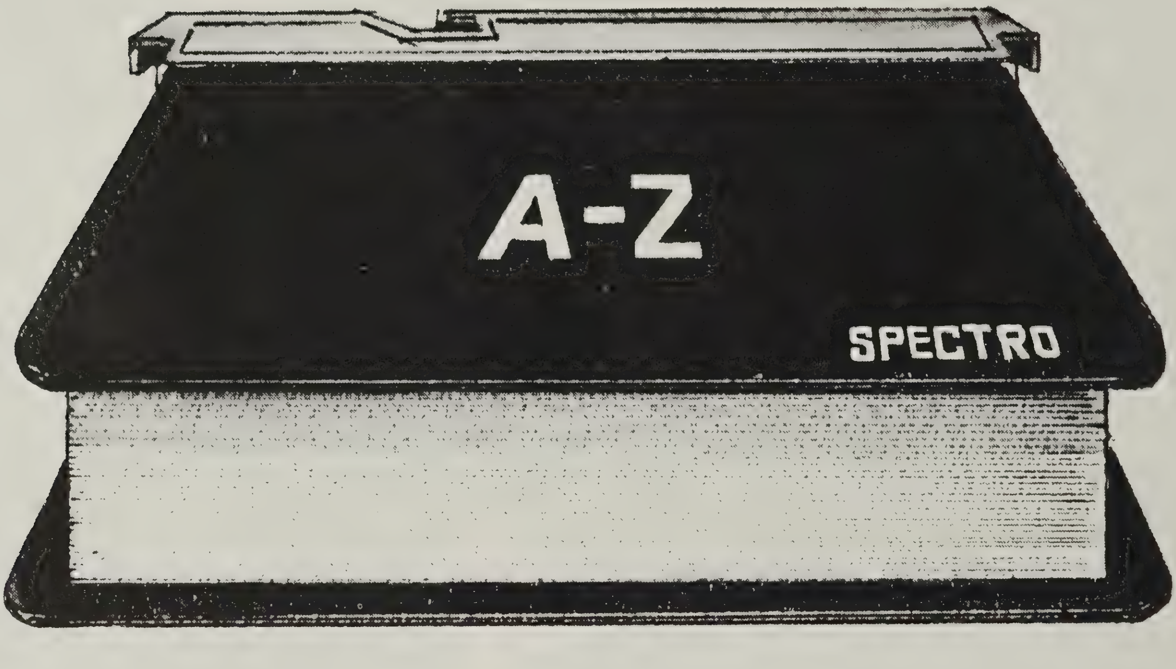

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Donald O. Fedder (left) Associate Professor and Director of Community Pharmacy programs for the School of Pharmacy accepts a check for $20,000 from the Merck Company Foundation from Frank X. Radigan and Brenda J. Abbott, District Managers of Merck Sharp and Dohme. The money supports the School's program, "The Pharmacist and Home Health Care for the Elderly."

John Hasty of Hayes, Virginia is the recipient of the "Pharmacist of the Year" Award from the Pharmacists Against Drug Abuse Foundation in recognition of his commitment to fight drug abuse in his community.

William F. Lalor has been appointed President of Stuart Pharmaceuticals and President of the newly created ICI Americans Pharmaceutical Group. Stuart is located in Wilmington, Delaware.

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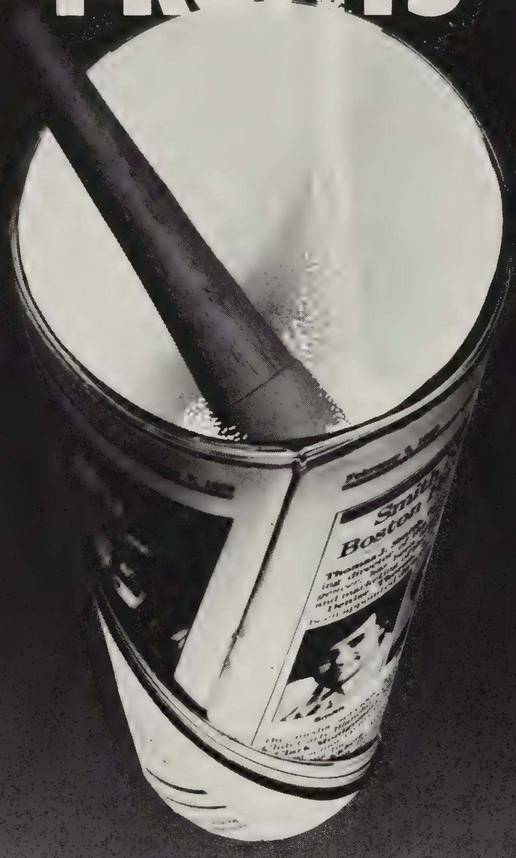

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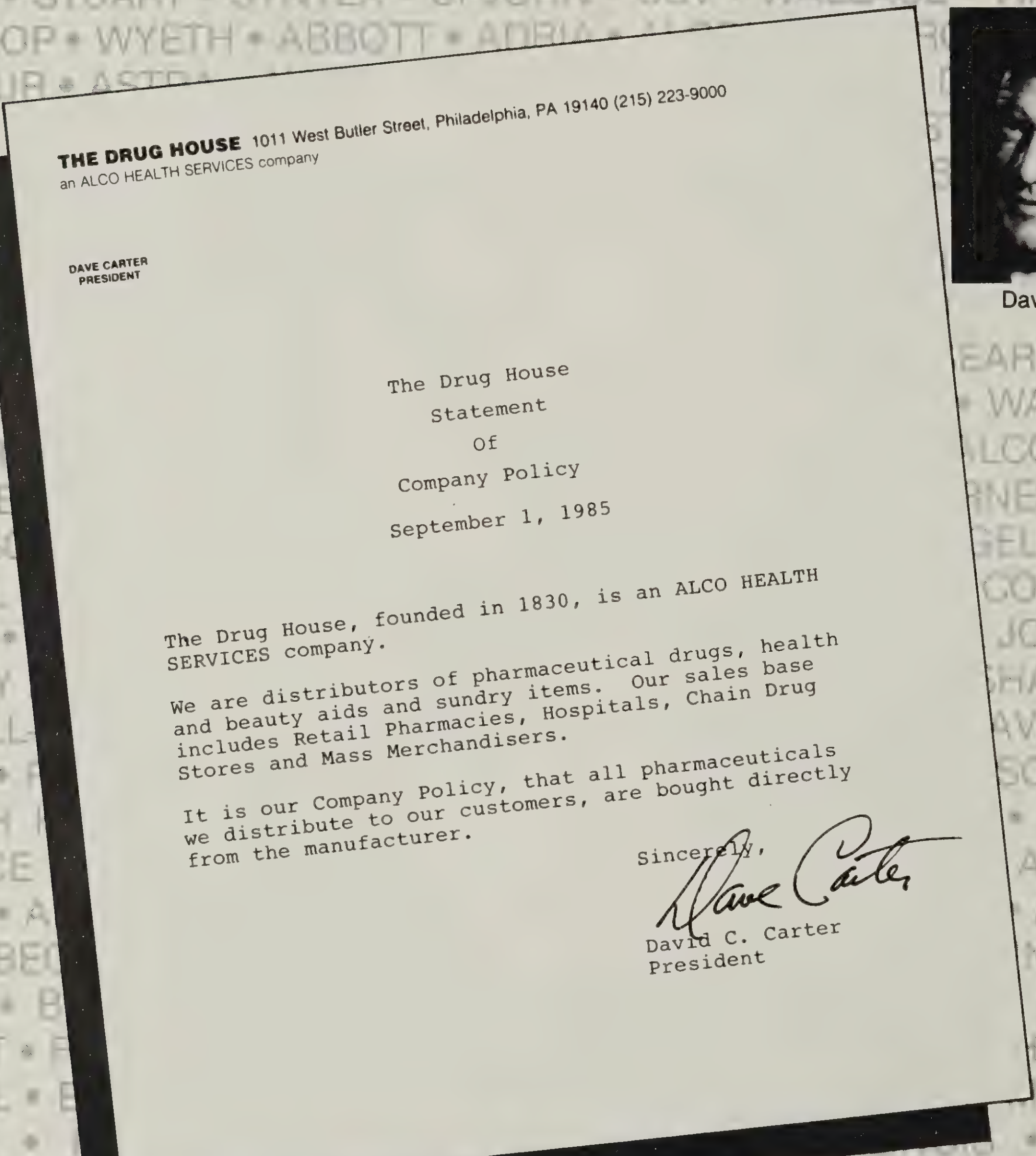

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THE
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Official Journal of
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Association

October, 1986
VOL. 62
NO. 10

Advising Consumers on Prickly Heat and Diaper Rash

—Thomas A. Gossel
—J. Richard Wuest

Diet and Cancer Prevention—An Elder Ed Talk for Pharmacists Flashback 1976 to 1986

—Estelle G. Cohen

Communicating with Patients

—Peter P. Lamy

Timely Topics: Cancer Nutrition and Elderly, Part III

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OCTOBER, 1986 VOL. 62 No. 10

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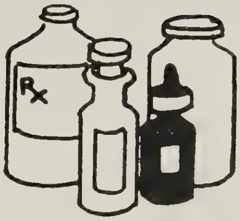
President's Message



> "Let both sides explore what problems unite us instead of belaboring those problems which divide us."
>
> John F. Kennedy

What a simple statement—what an accurate statement—right on the mark. Why, then, don't we adhere more to it.

Itemize, if you will—we are all pharmacists; theoretically, we are all operating for the common good. We are all Americans, all Marylanders. We would like to continue living and working here. We are all subject to the whims of government agencies, insurance companies, and the like. When one segment of our profession is injured, in the end, all of us suffer.

And yet, as a profession, we definitely lack a feeling of unity. Why should there exist this sense of antagonism because some of us are in community pharmacy, while others are in hospitals, or HMO's, or chains?

Without our knowledge and licenses, none of the aforementioned establishments could function. We have the power—and we don't even know it. Do we have the courage to exercise this power, or will we continue to allow non-pharmacists to determine our destiny?

> "United, there is little we cannot do in a host of new cooperative ventures. Divided, there is little we can do—for we dare not meet a powerful challenge at odds and split asunder."
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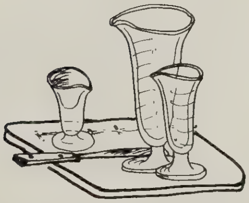

George C. Voxakis
PRESIDENT

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 9

Advising Consumers on OTC Products for Prickly Heat and Diaper Rash

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:
1. discuss the proposed causes and major prophylactic means for avoiding prickly heat and diaper rash;
2. present current thought on the medical management of these two disorders.

in the service of pharmacy

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Objectives

At the conclusion of this lesson, the successful participant will be able to:
1. identify the various types of prickly heat and explain their differences;
2. suggest how to best prevent and treat prickly heat;
3. compare and contrast the theories on causes of diaper rash;
4. suggest how to best prevent and treat diaper rash.

Rash commonly occurs as the result of excessive heating or occluding of the skin, or from leaving urine or feces-soiled diapers on infants or small children for extended periods. Diaper rash appears in adults and infirm patients who are incontinent and/or confined to bed. Prickly heat rash may also appear at any age during any season.

Pharmacists are often asked to recommend OTC products to treat both afflictions. Consumers also want to know what causes them and how to prevent them. Unfortunately, there is confusion between the two disorders regarding their causes, prevention, and treatment.

This month's lesson defines prickly heat and diaper rash. It provides the physiological basis for development of each disorder, and presents current guidelines for preventing and treating them. Pharmacists will also learn specific points of consumer advice to pass along.

Prickly Heat

Lesions of prickly heat (miliaria, heat rash) were described nearly 2000 years ago. Amelius Cornelius Celsus (25 B.C. to 50 A.D.) discussed pustules caused by sweating in *De Medicina*, and Pliny the Elder (23 to 79 B.C.) wrote of pimples caused by sweat in his *Natural History*.

Causes of Prickly Heat. Today we know that prickly heat is caused by obstruction of sweat gland openings. Sweat is trapped within the dermal layer causing localized irritation and inflammation, itching and generalized discomfort. The term "prickly" describes sensations variously referred to as "stinging" or "stabbing." The disorder is visible as clusters of pinhead-size bumps.

Prickly heat occurs most commonly during humid conditions with temperatures above 90°F and low wind velocity. It may appear during febrile illness when the skin is covered with heavy or obstructive clothing that causes intense sweating. Skin areas subjected to friction, such as the belt line, are especially vulnerable. The condition also occurs when individuals sit or lie for extended periods on rubber or plastic sheets which retard sweating. Thus, the disorder may occur at any age.

Types of Prickly Heat. There are several types of prickly heat. *Miliaria crystallina* describes the condition caused by sweat duct obstruction within the stratum corneum, just beneath the surface of the skin. A larger vessicle, 1 to 2 mm in diameter, forms over the skin surface. This condition occurs on the neck, axillae, and chest of infants, although it also appears on persons of all ages.

Lesions are usually asymptomatic until they are broken open by rubbing or scratching. Lesions filled with clear fluid, which can be easily broken with the fingernails, are characteristic of *miliaria crystallina*.

When obstruction occurs deeper within the epidermis, the disorder is termed *miliaria rubra* because of its red coloration. Miliaria rubra may be confused with contact dermatitis or drug eruption. It is the only form of prickly heat characterized by inflammatory lesions. Sweating causes small red nodules (solid bumps) that overlay red vessicles. Itching and burning quickly follow any event which induces sweating.

Miliaria profunda describes obstruction of the sweat duct within the upper dermis. This type predominately occurs on the trunk and upper legs. It results in flesh-colored or whitish papules. *Miliaria profunda* is often asymptomatic, and waxes and wanes with sweating.

Although sometimes referred to as "gooseflesh," *miliaria profunda* should not be confused with *cutis anserina*. This is an evanescent (i.e., disappears quickly) follicular disorder associated with cold and shock, rather than heat and sweating.

Any injury to the sweat duct can cause obstruction to sweat flow. The patient may remain asymptomatic until sweating is stimulated.

Prickly heat occurs more frequently in infants, geriatrics, and other persons with atopic disease than in young and middle-aged adults. *Miliaria crystallina* generally clears quickly without complications, with or without treatment.

Miliaria rubra may persist for two to three weeks while sweat ducts remain obstructed. With repeated skin damage, as from persistent scratching, additional pathology occurs leading to *miliaria profunda*. Secondary infection may occur with *miliaria rubra*, including impetigo and folliculitis. It is, therefore, important to keep affected areas clean at all times.

When widespread obstruction to sweating occurs, as when 50 percent or more of the body surface is affected, anhidrosis (cessation of sweating) may result. In hot environments when body temperature regulation depends on properly functioning sweat glands, this may lead to serious complications.

Treatment and Prevention. Miliaria is best treated by preventing any stimulus that initiates sweating. This is accomplished by remaining in a cool environment and avoiding heavy work or exercise. Air conditioning may help severely affected persons.

Clothing should be loose fitting, light-weight, and absorbent. Lying on a sheepskin mat, and removing plastic or rubber mattress covers are beneficial. During periods of prickly heat flare-up, plastic diaper covers (rubber pants) should not be placed on infants.

Cool sponge baths with a colloidal oatmeal product followed by application of a cooling skin lotion are helpful. Hydrocortisone 0.5% lotion or cream may help reduce local inflammation causing obstruction, but this should be reserved for persons two years of age and older, unless specifically ordered by a physician.

Diaper Rash

Diaper rash (diaper dermatitis, napkin rash, nappy rash) is a common skin irritation in infants. It reportedly accounts for up to 20 percent of all physician consultations for children five years of age and younger. In one study, approximately 35 percent of all infants experienced diaper rash. Incontinent adults may also suffer from diaper rash.

Diaper rash is different than prickly heat, although they may physically appear the same. Diaper rash is also occasionally confused with other cutaneous disorders including candidiasis, dermatitis, psoriasis, scabies, and herpes simplex. Specifically, diaper rash is a localized, red, inflammatory response that results from dermal contact irritation caused by urine, feces, or both.

Occasionally, the rash may appear on areas other than those in contact with a diaper, such as the arm or face. When this occurs, it represents involvement of some factor other than the primary affliction causing the diaper rash. These infants should be examined by a physician before being treated with OTC remedies.

Types of Diaper Rash. Diaper rash is categorized into four separate, distinguishable forms: chafing dermatitis, demarcated confluent erythema, discrete shallow ulcerations, and a beefy red erythema with confluent rash.

Chafing dermatitis is the most common type. It is characterized by mild redness and scaliness over the area in contact with the diaper. The discretely demarcated confluent erythema rash is confined to skinfold areas and sometimes has an associated white exudate present. Discrete shallow ulcerations, a third form of diaper rash, appears over the entire diaper area. A beefy red erythema with confluent rash is the form of diaper rash frequently associated with pustules. It is usually caused when the rash is compounded by infection with a fungus such as *Candida albicans*.

Causes. There are many theories supporting causes of diaper rash and even more proposed methods of prevention and treatment. It is unfortunate that the exact etiology remains unknown. However, most authorities believe the condition represents a type of irritant contact response.

Diaper rash develops when the skin remains in contact with urine or feces for an extented period of time. The precise component of urine or feces which initiates the problem remains elusive. A single component of either urine or feces, or a combination of substances may be responsible.

The first proposed cause of diaper rash was published in 1886. This theory stated that a strong ammonia odor was present whenever diaper rash appeared, so the problem was, therefore, due to ammonia. Today, many experts still adhere to this theory.

The evidence in favor of ammonia as the cause of diaper rash is strongly suggestive. For example, an ammonia-liberating bacterium *Brevibacterium ammoniagenes* can be readily cultured from urine of infants with the condition. Other microorganisms that can split urea to produce ammonia have also been identified. These are present in high concentrations in urine of affected individuals.

Conversely, the ammonia theory has been challenged by others. Some studies show that ammonia levels actually are the same in urines of affected and unaffected infants. Studies also reveal that when ammonia is applied with occlusion to the buttocks of infants over a 24-hour period, at concentrations five times that normally found in urine, it fails to produce an inflammatory response. Even *Brevibacterium ammoniagenes* and the other ammonia-liberating microorganisms have been reported in urine of infants who do not have the dermatitis.

A more plausible theory is that diaper rash is not caused by ammonia *per se*, but by a combination of components of decomposing urine.

These could be microbial or chemical. The ammonia odor may or may not be coincidental.

Fresh urine applied to skin of infants affected by diaper rash does not cause the problem. When it is allowed to stand at room temperature for several hours and is then applied, it can irritate the skin.

The yeast *C. albicans* is reportedly found on the skin of over 80 percent of all infants affected with diaper rash. When the skin's normal defenses are broken by other causative factors, the infection can occur.

Moisture *per se* does not cause diaper rash. It enhances microbial growth and thereby increases the chance for rash. The time period that a wet diaper must remain in place before a problem develops is unknown and probably differs with each infant. Frequent diaper changes both prevent and treat diaper rash.

The issue of pH is controversial. Some studies show that alkaline urine and feces left in contact with skin cause diaper rash, whereas acidic contaminants do not. The studies are not uniform, and their results are extremely variable. It is known that microbial growth is generally suppressed by an acid medium. When diaper rash is caused or aggravated by microorganisms, the local pH may be an important variable. Proponents of ammonia as an initiating factor raise the point that it is primarily responsible for raising the normally acidic urine to an alkaline pH. This is more irritating than recently voided urine.

Skin irritation may occur when diapers rub against the skin. Mechanical irritation may, therefore, play a significant role in development of diaper rash.

Prevention/Treatment. Because the precise cause of diaper rash is unknown, specific treatment is impossible. Prevention, therefore, is of utmost importance.

The need for frequent diaper changes must be stressed to parents. The diaper should be changed as soon as possible after it becomes wet. The diaper area should be thoroughly cleansed with warm water and a mild soap, and completely dried before a clean diaper is applied.

"Dry" diaper corners should not be used to wipe the baby's skin. Although they appear clean, they may contain millions of microorganisms. If the microorganisms are not removed by cleansing, the chance for infection is increased when the baby urinates the next time.

Infants who are highly susceptible to diaper rash may be placed on an open diaper during naps. Babies frequently urinate shortly after falling asleep. Therefore, they can be periodically checked and the diaper replaced if necessary.

Occluding the skin with rubber or plastic pants over the diaper should be avoided. These items are suitable for brief periods when the infant is away from home. Occlusion causes increased hydration of the diaper area.

Consumer-directed advertising strongly suggests that certain types of diapers are better than others. No study has demonstrated significant benefits of cloth over disposable diapers and vice versa.

Significant differences arise between commercially laundered and home laundered diapers. Commercial laundry services clean diapers at high temperatures which very effectively destroy all microorganisms. They also remove chemical irritants afterwards with thorough rinsing. These diapers are as clean and sterile as possible.

Parents washing diapers at home should use hot water followed with thorough rinsing and the hot cycle of the clothes dryer. Before washing diapers, soaking them in a household bleach solution (diluted as directed on the label) or vinegar (one cup vinegar in a half-filled washing machine tub) may help reduce the potential to irritate the skin.

The compounds listed in Table 1 are available over-the-counter for treatment of diaper rash. Products containing boric acid, including powders, ointments and solutions, have long been used. However, boric acid can be readily absorbed across inflammed and irritated skin and several infant fatalities have been reported from its use. For this reason, boric acid or products containing it should not be used to treat diaper rash.

Products containing quaternary ammonium compounds are sometimes applied directly to the skin, and others are used as diaper rinses. Some studies demonstrate that these substances reduce the occurrence of diaper rash; others show conflicting results.

TABLE 1

Representative OTC Products for Treating Diaper Rash

Product	Manufacturer	Form
Balmex Baby	Macsil	Powder
Desitin	Leeming	Ointment
Diaperene	Glenbrook	Cream Powder
Diaperene Peri-Anal	Glenbrook	Ointment
Mexana Medicated	Plough	Powder
Taloin	Adria	Ointment
ZBT Baby	Glenwood	Powder

Products containing hydrocortisone 0.5% are not indicated for use on infants less than two years of age. When they are used on older children, application should be restricted to less than one week to minimize the risk of systemic toxicity from absorption. Hydrocortisone treats symptoms without altering their actual cause, and a potential for toxicity due to absorption from occluded areas exists. For these reasons, products containing zinc oxide or another skin protectant should be tried before reverting to hydrocortisone.

One of the most popular OTC items used in diaper changes is talcum powder. Talcum may help soothe and dry moist skin, but is has not been proven that it actually prevents or treats diaper rash. Products containing corn starch should not be applied because this serves as culture medium for *C. albicans* which can worsen the problem

Overview

Prevention is the best treatment for both prickly heat and diaper rash. For the former, stimuli to sweating should be avoided as much as possible. For the latter, careful and meticulous detail to maintaining prompt diaper changes with frequent airing of the baby's skin are important.

Since neither disorder is overly serious in most cases, sometimes a cavalier attitude about prevention and/or treatment occurs. It is true that in most cases the disorders cause little more than discomfort, but complications such as secondary infection can result.

OTC products are useful to help prevent and to treat these afflictions. Persons using them should be aware

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of the limitations and the expected outcomes. There is probably no proven difference in various products in Table 1 that contain one or more ingredients. However, if one product fails to provide adequate relief, another one containing different ingredients could be tried. Persistent or long-standing conditions should be referred to a physician.

Poisoning Risk. The literature supports the belief that infants are at high risk of poisoning during diaper changes. One poison control center received inquiries in a three-month period relating to 138 exposures to potential poisons in children three years of age and younger. These children were being attended to at the time. One hundred twelve (81%) of these children ingested or inhaled one or more of 30 different substances by grabbing the product when the parent looked away. The remaining 26 children were given the item to hold while the diaper was being changed. Parents should be warned to keep dangerous items out of the reach of children during diaper changes.

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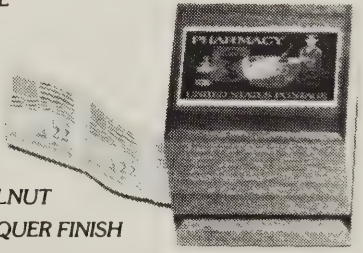

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"TIMELY TOPICS"

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CANCER, NUTRITION AND THE ELDERLY: A CLOSER LOOK AT SOME OF THE FACTS. PART III.

by
Peter P. Lamy Ph.D.
Madeline Feinberg, PharmBS

Specific Cancers

Breast Cancer: The dietary fat hypothesis is among the strongest, if not the strongest, risk factor for breast cancer that can be modified by an individual. It has been suggested that elimination of excess (20%) weight in post-menopausal women would reduce that incidence of breast cancer by 30%. It has also been hypothesized that early onset of menarche predisposes to breast cancer. Early onset occurs probably because of overnutrition *in utero* and early life. Perhaps vitamin E (as alpha-tocopherol) can reduce breast cancer via its antoxidant action, but this has not yet been proved.

Colorectal Cancer: Risk factors are ionized (free) fatty acids and biles salt, since they are irritating and toxic to the colonic epithelium. Other risk factors would be dietary fat and lack of calcium. A high fat diet increases the level of fecal bile acids, which then act as promoters of colon cancer through two mechanisms: a) directly, as tumor promoters, damaging the colonic mucosa, and b) by enhancing bacterial production of fecal mutagens. High intake of fat and sugars depleted of fiber (cakes, cookies) is thought to increase the risk of colorectal cancer by a factor of 3.6. Thus, while negative fiber intake and high fat intake seem to have been positively identified as risk factors, the role of calcium or its lack is still not clear. Decreased calcium levels can directly stimulate cell proliferation in cells undergoing neoplastic cell transformation. Calcium is necessary since it converts ionized fatty and bile acids to insoluble calcium salts. High calcium intake (1.25 g calcium as calcium carbonate) decreases cell proliferation in colonic epithelial cells and lowers cancer risk. A large-scale study does not support the findings that low calcium levels are associated with an increased colon cancer risk.

Esophageal Cancer: A low riboflavin status apparently increased the risk to this type of cancer, and a riboflavin deficiency also enhances the carcinogenicity of some drugs. On the other hand, though, a riboflavin-deficient diet depresses the development of mammary tumors.

Gastric Cancer: Pork, smoked meats and home-cured meats apparently increase the risk to gastric cancer, most likely because of nitrosamines. Nitrates, which are used to preserve these meats, are converted to nitrites and then to N-nitroso compounds, which are carcinogenic.

Other risk factors are salt, especially heavy use of salt as was found in the lower economic study population, and alcohol (red wine), both of which damage the gastric mucosa and increase cell proliferation. This study also identified increased carbohydrate intake as a risk factor, but probably not as a direct one. Rice, potatoes, pasta, corn bread, and candy, among others, probably act as risk factors because they lack a protective component, such as fiber content. A reduction of risk was seen through increased intake of fresh fruit and vegetables. Vitamin C was thought to have a protective effect, but not vitamin A.

Bladder Cancer: Smoking and coffee are risk factors.

Lung Cancer: It has been hypothesized that pollutants cause lung damage by inactivating alpha-1-antiprotease, as protective substance. This process is likely to be inhibited by vitamin E.

Ovarian Cancer: Eggs, three times a week and fried food, five times a week, are thought to increase the risk to ovarian cancer by a factor of three. However, this finding is disputed by the suggestion that it is not the eggs, per se, but the animal fats which are used to fry them. Vitamins A and E have not found a render a protective effect.

SUMMARY

While specific areas are still being disputed, and while there is yet a considerable lack of knowledge regarding the association of diet, nutrition, and cancer, it is clear that the recommendations by the National Cancer Institute make sense. It is also clear that patients ought to be warned from overuse of specific substances in an attempt to prevent cancer in later life.

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Elder-Ed Talk based on this Series beginning on Page 10.

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134th APhA Annual Meeting
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DIET AND CANCER "PREVENTION"

(Sample Elder-Ed talk for Community Groups)

- I. Introduction
    - A. Introduce self
    - B. "What are some of the things we do that may increase our chances of getting cancer?" (what does audience already know?)
        - smoking
        - radiation exposure (X-rays)
        - eating certain foods (charcoal cooking)
        - etc
    - C. What causes cancer? (ask) (explain)
        - what actually causes cancer may be hard to prove
        - often exposure to cancer-causing agents (carcinogens) may take place 30 years or more before actual disease occurs
        - 80% of cancers may be related to our environment
        - 35% may be related to what we eat
        - most important: causation in cancer is hard to prove
    - D. What can we do to minimize our risk?
        - avoid exposure to known cancer-causing substances
        - may be able to alter eating habits to help reduce risk.
- II. Association between dietary patterns and cancer
    - A. Foods to avoid
        - may promote changes in cell which increase risks
    - B. Foods to eat
        - may inhibit formation of cancer-causing substances
    - C. May reduce risk to other diseases (e.g. heart, digestive, etc)

Guidelines on dietary patterns (National Cancer Institute and American Cancer Society)

- III. FIBER
    - A. Eat fiber-containing foods!
        1. fibers—nondigestible or partially digestible materials from plant sources
        2. contains many different kinds of fibers
        3. some types of fiber may offer protective effects against colon & rectal cancer
    - B. How it may work
        1. may reduce the amount of carcinogenic substances present in bowel by
            - increasing bowel movements
            - changing chemical balance in colon
    - C. Recommendation
        1. dietary intake of fiber should be 25–35 g/day (current estimates for Americans 10–20 g/day)
        2. eat variety of food sources containing fiber
        3. avoid fiber supplements unless doctor orders! (fiber-rich *foods* are protective, not just the fiber component).
        4. foods high in fibers: whole grain
            - whole grain products
            - fruits (apples, apricots, bananas, berries, pineapples, papayas, prunes, raisins, oranges)
            - vegetables (carrots, broccoli, corn, cauliflower, celery, squash, spinach, potatoes, greens)
            - dried peas and beans
- IV. Foods rich in Vitamin A
    - A. "Foods" are important, not Vitamin A alone
        1. scientists observed protective effects from diets rich in Vitamin A containing foods
        2. therefore, cannot recommend Vit. A supplement alone
        3. there may be one or more components in food sources high in Vit. A responsible for protective effects

DIETARY GUIDELINES

Eat high fiber foods: High fiber foods are important to good health

Eat foods low in fat: Some types of cancer are associated with high consumption of fats. Foods low in fat: fish, chicken, leaner cuts of meat, low-fat dairy products

Eat fresh fruits and vegetables. Dark green and yellow vegetables: broccoli, carrots, cauliflower. Fruits rich in vitamin C, carotene and fiber: oranges, cantaloupes, apples

Eat a well-balanced diet and avoid being over- or under-weight: Obesity is associated with a high mortality from many types of cancer

---

*National Cancer Institute

4. two sources of Vitamin A:
   - vegetable products (rich in beta-carotene)
   - animal products (rich in pre-formed Vit. A, called retinol)
5. Beta-carotene may have more protective effect
6. *Warning!*—too much Vitamin A can cause toxicity and may cause abnormal cell changes (observed in animal experiments).

B. How it may work
1. needed for normal cell growth, particularly epithelial cells (mucus membrane type cells in body)
2. if Vitamin A is deficient, may increase number of abnormal cells forming
3. may protect cells against effects of cancer-causing substances
4. Vitamin A may be protective in reducing risk to cancers of lung, liver, bladder, breast, GI, larynx, oral and skin

C. Recommendations
1. eat foods rich in Vitamin A
   - dark green leafy vegetables
   - yellow-orange vegetables
   - yellow-orange fruits
   - dairy products
   - liver
   - fish (oily fish good source of retinols)
2. Save the *cooking water* (Vitamin A goes into cooking water)

V. Vitamin C

A. "Foods" are key word, not vitamin supplement

B. How it may work
1. may reduce formation of cancer-causing substances (nitroso-compounds) in diet
2. N-nitroso compounds are substances formed during digestion of smoked meats, e.g. bacon; or charcoal broiled meats
3. Vitamin C may be protective in reducing cancer of stomach and esophagus
4. *Warning!* Individuals with history of gout or kidney stone formation may need to talk with doctor before changing dietary patterns

C. Recommendations
1. eat fruits and vegetables from following groups
   - dark, green leafy vegetables: broccoli, kale, spinach, romaine, endive, chicory, escarole, water-cress, collard and mustard greens
   - yellow-orange vegetables: tomatoes, squash, sprouts
   - citrus fruits: orange, lemons, limes, grapefruits
   - juices from fruits
2. Key is "Fresh!" Vitamin C easily destroyed in cooking and storage and during prolonged exposure to air and light

VI. Dietary Fats

A. High-fat diets, particularly diets high in certain unsaturated fats, may need to be reduced
1. average American diet may be as high as 40% fat
2. should be reduced to 30% of total diet
3. two types of dietary fats
   - unsaturated (vegetable and fish sources, usually liquid at room temperature)
   - saturated (animal sources, usually solids at room temperature
4. unsaturated fats of vegetable origin, may increase risk to certain cancers
5. unsaturated fats of fish origin, omega-3 fatty acids, may offer protective effect
6. *Warning!* saturated fats need to be reduced to lower risk to heart disease and atherosclerotic disease

B. How it may work
1. many theories, but diets high in unsaturated fats of vegetable origin may increase risk to breast cancer
2. other factors involved, such as caloric intake, obesity factors, and total fat intake, but overall may reduce risk to breast, colon, gallbladder, and uterine cancer

C. Recommendations
1. reduce total fat intake by increasing amount of food eaten from other food groups
   - cereals
   - vegetables
   - fruits
   - low fat meats and fish
   - reduce fried foods
   - cut down on fats, creams, rich sauces

VII. Reduce Caloric Intake; Avoid Obesity

A. Overnutrition may increase risk to cancer
1. may be a combination of total calories, total fat intake, and energy expenditure (exercise) which are all involved
2. Maintain "ideal" body weight to reduce risk

B. How it works
1. much of research in laboratory animals indicates that there is a relationship of total calories, and fat intake involved in increased risk to colon, uterine, breast and gallbladder cancers.

C. Recommendations
1. maintain ideal body weight by reducing total number of calories from all food groups
2. maintain activity

VIII. Alcohol

A. Excessive intake associated with increased risk to cancer of mouth, larynx, esophagus and liver

- B. How it works
  - 1. may be direct irritant (?) to mucus membranes
  - 2. may promote liver/cell changes since alcohol is metabolized in liver
- C. Recommendations
  - 1. moderation, at the very least!

IX. Salt-cured, Smoked and Nitrite-cured Foods

- A. Reduce intake smoked foods
  - 1. may be due to processing and incomplete combustion which contain cancer-causing substances
- B. Reduce intake of cured and pickled foods
  - 1. contain high amounts of nitrate and nitrite which enhance formation of nitroso-compounds that are known carcinogens
  - 2. Nitrite, once used in this country as a preservative, has been taken out of food processing industry.

X. Other Topics of Interest with No Specific Recommendations

- A. Vitamin E
  - may be anti-oxidant and reduce certain cancer-causing agents found in cells
  - diets with vegetable oils, grains, eggs in moderate amounts provide adequate Vitamin E
- B. Selenium
  - evidence very limited as to role of selenium in reducing risk
  - Warning! Excessive use is toxic and any medically unsupervised use of selenium supplements is not recommended
- C. Coffee
  - no indication that caffeine is a risk factor
  - studies are inconclusive regarding use of coffee and occurrence of bladder or pancreas cancer
  - no recommendation made against *moderate* use of coffee at this time
- D. Foods broiled or fried at high temperatures
  - cooking meats under these conditions give rise to products which, in bacteria and in a few animal tests, have been shown to be cancer-causing
  - no recommendations given at this time
- E. Artificial Sweetners
  - saccharin use shown to cause bladder cancer in mice, but no clear evidence for role in human cancer
  - long-term effects of new non-sweetners not known
- F. Food Additives
  - used to prevent spoilage, improve color and flavor
  - some found to be cancer-causing and removed from market
  - some found to be protective against cancer
  - no specific recommendations at present

XI. Conclusions

THERE ARE NO GUARANTEES THAT, IF YOU FOLLOW THESE DIETARY GUIDELINES, YOU WILL NOT GET CANCER. These are recommendations which, if followed, may reduce your risk!

Gilbert N. Weise Presented Victor H. Morgenroth, Jr. Memorial Award

Gilbert N. Weise, immediate Past-President of the American College of Apothecaries, was presented the Victor H. Morgenroth, Jr. Memorial Award at the College's 46th Annual Conference conducted August 13–17, 1986 in Toronto, Ontario, Canada. The presentation was made during the President's Banquet on Saturday evening, August 16th, by Joseph Dilger, Director of Professional and Trade Relations for Parke-Davis and Company, sponsor of the Award. The award consists of a beautifully framed print of Andrew Craigie, America's first Apothecary General, plus a $1,000 contribution in the Past-President's name to the Research and Education Foundation of the ACA. This contribution will establish Weise as a Life Member in the Foundation.

Gilbert N. Weise is the owner of Weise Prescription Shops in Jacksonville, Florida. He received a B.A. degree in Psychology from the University of Virginia in 1958 and a B.S. degree in Pharmacy from the University of Florida in 1960.

Mr. Weise is very active in local, state and national professional pharmacy associations. He served as President of the Duval County (Florida) Pharmacy Association for 1965–67, the Northeast Florida Pharmaceutical Association for 1971–72, the House of Delegates of the Florida Pharmaceutical Association for 1974 and the Florida Pharmaceutical Association for 1976–77. Committee activities include the Public Affairs Committee, Organizational Affairs Committee and Professional Affairs Committee of the American Pharmaceutical Association; the Executive Committee of the Academy of Pharmacy Practice of the American Pharmaceutical Association; and the Governmental Affairs Committee of the National Association of Retail Druggists. Additionally, he served as the Director of the Florida Pharmacy Political Action Committee from 1978–82.

Academically, Gilbert Weise is an Adjunct Professor at the University of Florida College of Pharmacy, and often a guest speaker at Florida A & M College of Pharmacy. He served on the Review Committee for the *Handbook of Non-Prescription Drugs* in 1981, the Editorial Board for *Patient Counseling in Community Pharmacy* since 1982 and published *A CRT System For The Community Pharmacist* in 1978.

Our 1986 Pharmacy Consultant Panel gave us a good, hard look from eleven very critical vantage points: Their personal experience in pharmacy.

Some things they told us made us feel proud. Some things made us see the need for change. Most importantly, they pointed us in some exciting new directions. The result? A better understanding of the way things are, and should be, for both you and your customers.

They might have spared our feelings by telling us what they thought we'd like to hear.

But they didn't. And we're glad.

Meet our 1986 Pharmacy Consultant Panel.

Standing Left to Right:

Charles Lippert, Pharmacist
President
Evans Pharmacies Inc.
Zeeland, Michigan

Reed Rosling, Pharmacist
Vice President
Hospital Sales
Bergen Brunswig Drug Co.
Orange, California

John Kogut, Pharmacist
Senior Vice President
Fay's Drug Company
Liverpool, New York

Marily Rhudy, Pharmacist
President
Continental Pharmacy
Topeka, Kansas

M. Patricia Lee, Pharmacist
Director of Pharmacy
University of California
San Diego Medical Center
San Diego, California

Seated Left to Right:

Jack R. Cole, Pharmacist
Dean, College of Pharmacy
University of Arizona
Tucson, Arizona

Darwyn Williams, Pharmacist
President
Williams Drug Inc.
Webster City, Iowa

William Thien, Pharmacist
Vice President
Health Services and
Pharmacy Operations
Walgreen Drug Stores
Deerfield, Illinois

John Piecoro, Jr., Pharmacist
Associate Director
Clinical Services
Chandler Medical Center
Lexington, Kentucky

Bernard Mehl, Pharmacist
Director of Pharmacy
Mount Sinai Hospital
New York, New York

Not pictured: Larry Braden, Pharmacist, Executive Vice President, Georgia Pharmaceutical Association, Atlanta, Georgia

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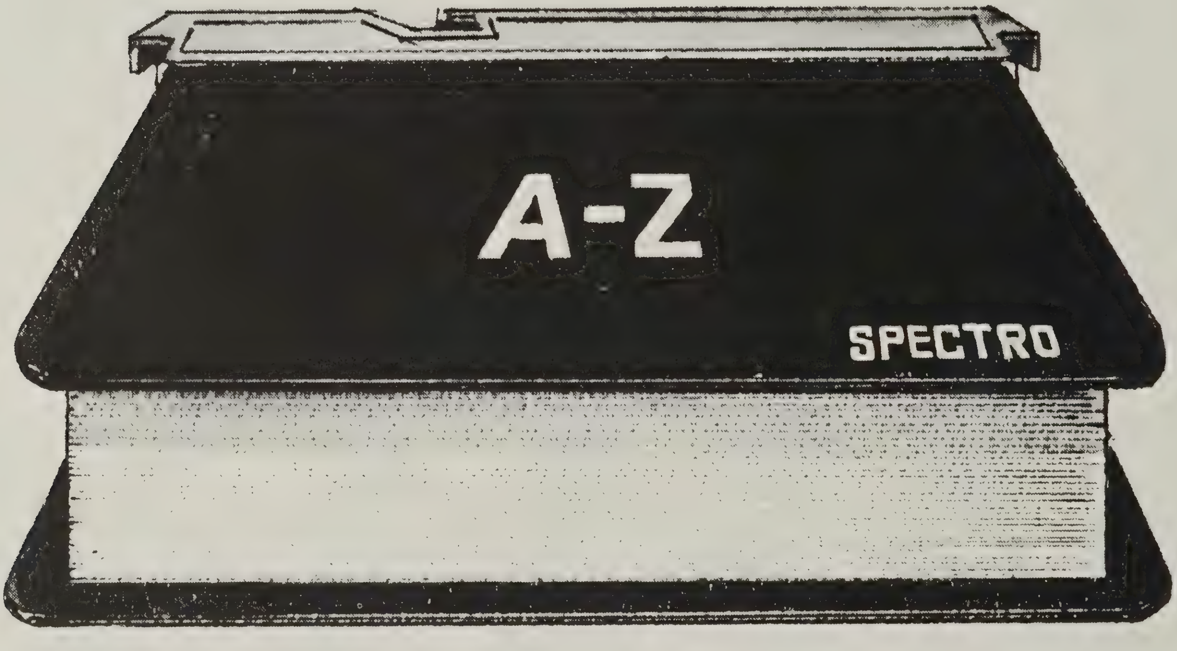

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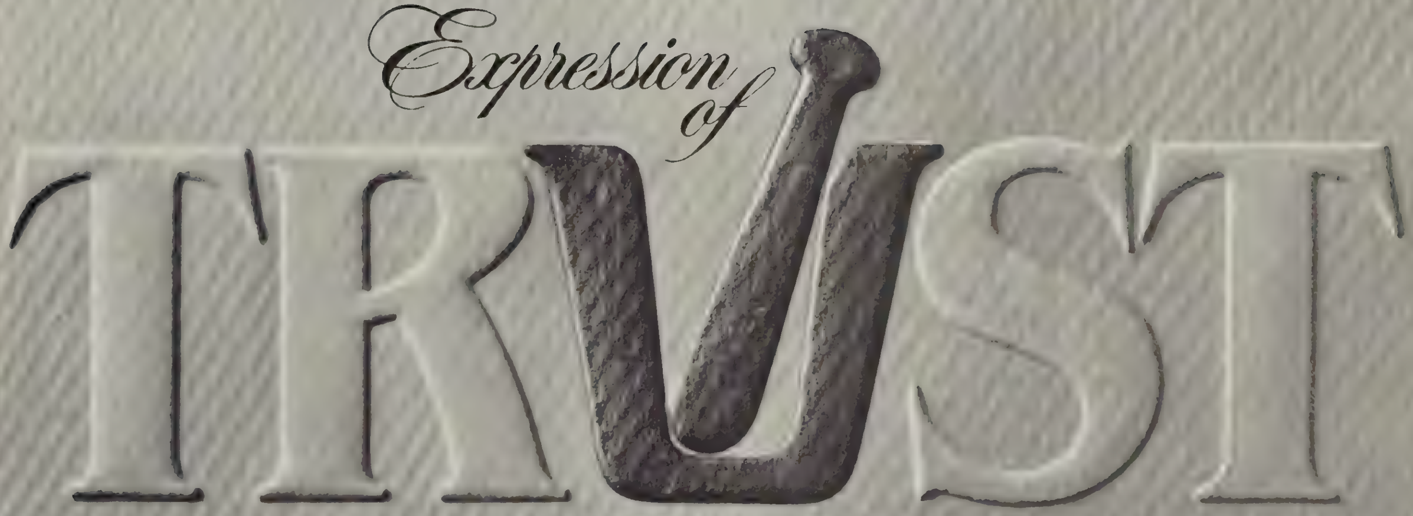

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Flashback 1976 to 1986

by Estelle G. Cohen

The timing could not have been better. I entered the world of pharmacy in 1976 when change in pharmacy was so forceful an imperative that I was immediately caught up in the excitement it created. Pharmacy was redefining itself, asserting itself. Now that I am ready to step down from my post as the public member of the Maryland Board of Pharmacy, pharmacy has redefined itself and re-established its professional roles even though change continues to be the order of the day.

When I came to pharmacy I was ignorant of the totality of the role the pharmacist was educated to assume. I did not know that pharmacists could serve as a vital link in the delivery of health care, but then neither did most other people including other health practitioners. Here was the pharmacist, providing a rich resource for society albeit an extremely underutilized resource; and I was about to witness his emergence as a more assertive, more fulfilled health care practitioner.

The fault of ignorance did not lie with the public and other health professions. Rather it resulted in part from the philosophy widely taught in the nation's pharmacy schools in the 1940's and 1950's. It was during this time that the colleges actually discouraged pharmacists from interacting with the patient! It is only since the 1970's that their philosophy underwent change aimed at lifting pharmacists out of their so-called traditional product-oriented role into the role of public health care providers. In fact in the 1970's interested parties were attempting to determine and explain just what is meant by the term ''clinical pharmacy'' a term that was gaining increased usage.

In 1971, Kenneth N. Barker, who was then Director of Administrative Research for the United States Pharmacopeia and Ph.D. in pharmacy administration, and Joseph G. Valentino, USP Executive Associate and a pharmacist and a lawyer, addressed the American Society of Hospital Pharmacists at the American Pharmaceutical Association meeting in San Francisco. Their presentation entitled ''On a Political and Legal Foundation for Clinical Pharmacy Practice'' and reprinted in the ''Journal of the APhA'', May, 1972, set forth the pharmacy changes of the 70's that did eventually materialize. Their purpose appears to have been to prepare the way for the clinical practice of pharmacy to become the norm for the future practice of pharmacy.

Barker and Valentino told why the yet undefined term ''clinical pharmacy'' was enjoying new popularity in 1971. ''Perhaps one of the main reasons for the current popularity of the term clinical pharmacy is the fact that it has, up to now, successfully eluded precise definition and thereby avoided offending or threatening anyone very seriously.''

Barker and Valentino noted that though dictionary definitions of the word ''clinical'' differ, all of them agree that direct contact with a person or persons is basic. It was a premise of their paper that there is concensus that a fundamental function of clinical pharmacy practice, whether it be at the bedside or across the counter is the counseling of patients regarding their medications.

But, the authors noted, political and legal problems stood in the way of the advance of that concept. The pharmacy laws on the books at that time declared that the task of counseling patients about their prescription medications was part of the physician's practice, not the pharmacist's. State pharmacy laws would have to be changed to legally protect the pharmacist when he/she did counsel patients. The law would have to state clearly that the giving of such advise is a recognized pharmacy act.

It is good to report that in our state, the Maryland Pharmacy Act was one of the first to recognize a duty of the pharmacist to provide information, but primarily to the physician rather than the patient. (former Article 43, section 250). This was revised in 1980.

Not just the law had to be changed—attitudes of pharmacists had to be changed. For example, Barker and Valentino reported on the ''Code of Ethics of the Maine Pharmaceutical Association'' to wit:

> ''The pharmacist shall not discuss the therapeutic value and/or effect of a prescription with a patient or disclose details which the prescriber has withheld. He should suggest to the patient that such details can be properly discussed with the prescriber only.''

It seems that our writers were not optimistic about the ease of changing state practice laws or attitudes. They said:

> ''Existing state practice laws are not likely to be changed by pharmacists at the expense of medicine [AMA was politically stronger than APhA]. It is politically unrealistic to hope so.''

Pharmacy needed broader political support, they felt, in order to change state laws. There were national pharmacy organizations such as the ASHP, NABP and others that might have the clout to affect change. It

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Estelle was the first consumer member of the Maryland Board of Pharmacy. See the picture of the Board of Pharmacy members on page 29.

could happen, said Barker and Valentino, but it was not likely.

The concept of clinical pharmacy began to separate pharmacists in the 70's into different categories, resulting in more than one voice on pharmacy matters. In fact it would appear that a main thrust of Barker and Valentino's address was to persuade the American Pharmaceutical Association to actively support the concept of clinical pharmacy. They said:

> "The term clinical pharmacy has been troublesome to APhA, because, to the extent it tends to divide pharmacists rather than bring them together, it conflicts with APhA's primary long range goal of becoming the 'one voice for pharmacy'. This is the case when clinical pharmacy is equated with the specialty of hospital pharmacy, or when certain pharmacists propose to identify themselves as 'clinical pharmacists' practicing the specialty of clinical pharmacy."

Barker and Valentino itemized specific events that suggested the interpretation of the law was already changing and that it was no longer entirely the physician's province to determine what and how much to tell a patient about a prescription drug. One indication was the then new Food and Drug Administration (1970) requirement that pharmacists make patients aware of the information pamphlets that accompany oral contraceptives; thus, the pharmacist had to communicate with patients even if he had not done so previously.

The state of flux in pharmacy provoked the writers to propose a way to expedite the concept of clinical pharmacy. They felt that support for clinical pharmacy from the USP and the NF (National Formulary) would give pharmacy a legal foundation for change. The inclusion in these publications of patient information that a pharmacist might tell the patient at his discretion without securing prior approval from the physician would help to refute charges that the pharmacist was interfering with the physician—patient relationship in giving information to the public.

Both the USP and the NF were specifically designated as official compendia in the Federal Food and Drug Act. Both had and still have the authority to establish legal standards for drugs that are then enforced by the FDA. (Since 1975 the USP and NF have been merged as a result of purchase of the NF from the APhA.)

Four years after this article was written (1975) the first USP that gave patient drug information was distributed. The dispensing information in it was limited and basic but this was a big step to be taken for pharmacy and other health professions. As the information was expanded, health professions were upset by the new USP because they feared increased liability and they wanted the information in a separate "nonofficial" book, not USP itself.

In 1980 the USP Convention published the first USP DI (Dispensing Information). This has expanded into a 2-volume set: Volume I is *Drug Information for Health Care Provider* and Volume II is *Advice for the Patient*. This seems to satisfy health care providers and it gives them ease of reference from an "authorized" compendium.

In a more recent paper "Recognition of the Pharmacist's Consultant Role Under State Pharmacy Practice Acts and Regulations" (revised 11/19/81), Valentino reviewed the laws and regulations of forty-eight states, the District of Columbia and Puerto Rico. He found wide variation with laws running the gamut of some states having no reference to pharmacist's consulting role, some still with language in their laws which seemed to be negative toward patient consultation and some states that appeared to encourage the consulting role such as the revised (1980) Maryland Pharmacy Law. This law states [section 12-101 (j)(1)] that the practice of pharmacy means to engage in providing information and explanation to patients and health care providers about the safe and effective use of drugs and medical devices as well as appraising drug therapy. Many states have adopted NABP's Model Pharmacy Act which states that it is the responsibility of the pharmacist to advise where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devises.

Unless there is agreement in the state pharmacy laws and in the medical community on the pharmacist's responsibilities vis-a-vis the patient, the final word on clinical pharmacy may be written by the courts of law. As Valentino has pointed out if pharmacists are to have a professional consulting responsibility, a commensurate degree of liability is inevitable.

In 1986, Valentino mentions in his "Address to the Graduates of Rutgers College of Pharmacy May 22, 1986" that the courts are struggling with the role of the pharmacist relative to patient counseling. A recent decision handed down by the Superior Court of Pennsylvania illustrates the court's hand in defining the pharmacist's role. In this case a pharmacist lost his appeal. Previously a trial court had determined that the pharmacist and a physician had incurred joint liability when the physician prescribed and the pharmacist dispensed Cafergot. Both failed to give the patient adequate instructions thus resulting in patient injury. Each health professional's activity or lack of activity reenforced the other's failure to instruct the patient. The court indicated "Each has an affirmative duty to be to a limited extent, his brother's keeper".

In the mid-1980's pharmacists are receptive to an active clinical role, though not all pharmacists or all pharmacy administrators are. Some pharmacy administrators discourage clinical pharmacy even when their pharmacist personnel are geared to interact with patients.

The introduction of poison centers throughout the country and passage of generic substitution laws and the public's quest for more information about the drugs they utilize have been instrumental in impelling change in pharmacy law. These factors have also helped to acquaint the public with the pharmacist's role in health care.

New pharmacy specialties have come alive in the 70's and early 80's including pharmacokinetics, psychiatric pharmacy, nutritional pharmacy, oncology pharmacy, consultant pharmacists and home health care. New working relationships have developed between some pharmacists and physicians in institutions and in the marketplace. New academic degrees are conferred by pharmacy schools. We have seen women enter the profession in large numbers. Electronic technology is now facilitating patient profile management and portends greater and swifter access to pharmacy data bases.

The years have witnessed the loss of many independent pharmacies and the growth of chain pharmacies. Today, since most of the graduating pharmacists are employed by chain pharmacies, their corporate policies will most probably dictate the direction clinical pharmacy will take on the community level. If consulting pharmacy can be made more profitable, its chances of becoming the norm for the practice of pharmacy are enhanced. If not, many new pharmacists may experience frustration on the job and the public will be receiving second class pharmacy.

In Florida, pharmacists are prescribing drugs. Florida's new pharmacy law presages a trend toward the continuing expansion of the role of the pharmacist. Physicians may resist this expansion especially as medicine becomes more competitive and less lucrative. More physicians are dispensing drugs in their offices. The AMA is currently becoming more protective of its physicians.

Now may be the time for all good pharmacists to come to the aid of their profession—as never before. Physicians and insurers will be watching closely for future change and so will I. The more that clinical pharmacy is exercised, the healthier the public will be.

Peer Review Committee
Year End Report

Beverly Yachmetz

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—$.02 per coupon; 500 to 1000 coupons—$.02.5 per coupon; and batches of 1000 coupons and over—$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.

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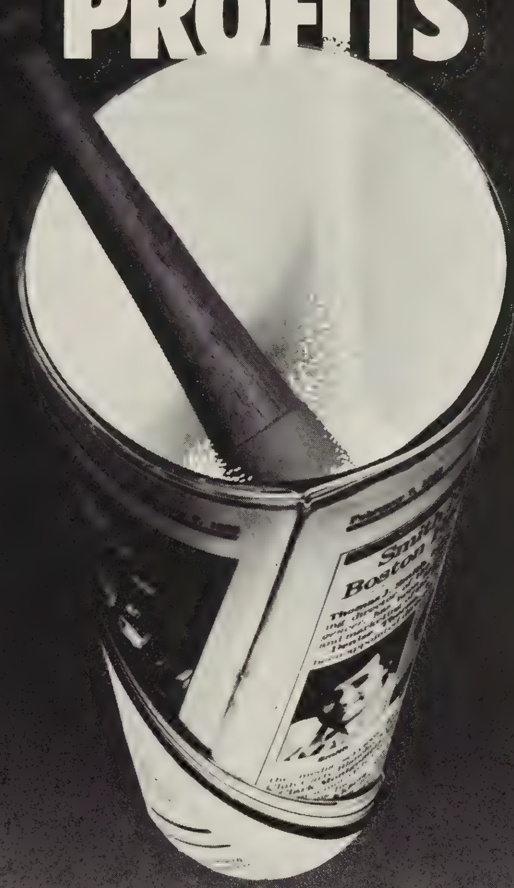

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COMMUNICATING WITH PATIENTS

by
Peter P. Lamy, PhD

Symposium on "Importance of Counseling and Building the Professional Image of Pharmacy", New York City, February 4, 1986

". . . communication is the act of the recipient

Peter Drucker

Information is increasingly ignored, misinterpreted or handled arbitrarily.

Introduction

From today's vantage point, a clear evolution in the pharmacist's approach to communications with patients and the pharmacist's responsibility in communicating with patients is apparent. Where once pharmacists would type labels which reflected exactly the physician's instructions written on the prescription, they are now concerned not only with expanded drug-related information, but the delivery of that information and its effectiveness (does patient understand and *can* and *will* patient cooperate in the therapeutic regimen?). Pharmacists must be well-versed in and be willing to relate to the patient therapy-related information (exercise and dietary information, etc.) and be ready to assist patients in the identifying community resources that might enable a patient to fully meet the purpose of a therapeutic regimen and enhance the therapeutic outcome.

To accomplish this, the pharmacist must establish a partnership-like relation with the patient and a high level of rapport and mutual trust.

Communications

Emphasis in the past has too often been on *teaching* and not necessarily on *learning*. Clearly, communicating is not simply the dissemination of information, but it is a system, an approach that includes an assessment of a particular patient's needs and selection of a particular approach. One must identify what needs to be taught, then see that the patient learns it, and finally assure that the patient is willing to apply the learned knowledge. Only information exchange is fully effective, i.e., the provider needs information from the patient and in turn, the patient (and others) needs information from the pharmacist. Effective information no longer includes only drug-specific data, but must be expanded to include a host of health-care and disease-prevention information, as well as information on various enabling factors. To be effective, the pharmacist must know the patient, the patient's status, and the patient's health beliefs. As the needs of the patient population change, the pharmacist's role in the information process will continue to change and evolve. If current predictions hold true that by the end of the century almost 50% of all chronic care drugs (for example: cimetidine, hydrochlorthiazide, propranolol) will be available OTC, then an expanded role of the pharmacist in the process of health care information is clearly mandated.

The Purpose of Communications

Communications are needed to help patients (and others) to understand a particular regimen, its goals, promises and limitations. Communications are necessary to help motivate and encourage the patient to participate fully in an agreed-upon regimen, in an informed and intelligent manner. Communications are necessary to help remove barriers and stress enabling factors. Communications are necessary to help the provider (the pharmacist) understand the patient and the patient's motivation, health beliefs, social and health status, and many other factors.

Communicating with Whom?

The communication process between the pharmacist and the community-at-large and individuals in the community should start long before the customer becomes a patient. This helps to establish the pharmacist as a health care professional and helps to form rapport and trust between pharmacist and potential patient at a time when immediate concerns about a particular disease and its outcome do not overshadow everything else.

This can be accomplished by participating in health fairs, in diabetes-detection campaigns, hypertension-detection efforts, anti-smoking campaigns, community drug reduction programs, by attending meetings of ostomy and epilepsy groups to answer questions and concerns, and participating in drug-abuse programs, particularly in elementary and high schools.

Individual efforts, with already-established "customers" may take a different effort. Pharmacists may establish rapport with specific families by noting births,

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weddings, and other instances of family life. They can advise on potential problems with travel to foreign countries. They should also be available as information source on current concerns of consumers, such as wellness programs, osteoporosis, and advice on other public health issues. This, however, imposes on the pharmacist to be current on news that may worry the customer, such as the recent announcement that the Citizens Public Health Group has asked the HHS Secretary to ban use of piroxicam for patients over 60 years of age. Is piroxicam dangerous for these patients? People may ask about news releases on new drugs or treatments and, indeed, they often do.

Then there are specific groups of consumers who are not patients but who do need advice and counseling.

In pediatrics, there has been established the concept of the "therapeutic triangle", since the pharmacist deals with the parents and not the patient. The pharmacist must establish with them special information needs and concerns.

Caregivers, the informal family structure that gives support to house-bound or bed-bound patients, are a rapidly growing group that needs help. Among patients cared for by them are the handicapped and the elderly. In those instances, the pharmacist knows little about patient motivation and cannot given encouragement directly, often even being unable to communicate with the patient by telephone.

TABLE 1
The Changing Face of Communications

First Phase:	Write label as instructed by physician
Second Phase:	Write label but elaborate and explain written label directions Add: Auxiliary labels
Third Phase:	Add verbal instructions. Reinforce label instructions verbally. Does patient understand?
Current Phase: Pharmacy begins to evolve into a health-care profession.	More "patient-specific" efforts. Increased and expanded efforts, including non-drug related but therapy-related information: exercise, nutrition, smoking, alcohol. Use of audio-visual aids. Does patient understand and *can* and *will* the patient cooperate (change from compliance to mutually-agreed-upon cooperation). Difficulty: computer-assisted dispensing, "no time".
Future Phase: Pharmacy continues evolvement	Patient-provider partnership-like relation and trust. More targeted efforts: acute care vs. long-term care efforts, further expanded information base: community resources, target care-giver. In view of greatly enlarged availability of OTC drugs, new efforts and possibly different efforts will be needed. Needed: approach to "medically-assisted self-care". Target "patient-at-risk". Target "preventive care" efforts. More information exchange between providers (chronic care) and more information between hospital and community pharmacies (particularly in immediate post-hospital home care)

Caregivers must understand the need for observation of drug effects and how and when to report them. They must understand the changing nature of some diseases, and special patient needs. They, themselves, may indeed be patients. More and more, one encounters family caregivers who are old themselves and often functionally limited. Often, they are working daughters, with families of their own, the so-called "woman in the middle" or "sandwich" family. Chronic poor health of the dependent person often afflicts those caring for them. "Burn-out" is not uncommon, and serious depression has been found in 25% of caregivers, who often may well be in a permanent state of physical and mental exhaustion. The "burden of care" speaks to the stress that caregiving can induce in the care-giver, and the burden has been rated as "severe" in 40% of families providing caregiver services. Excessive amount of time necessary to care for the dependent family member (perhaps a mentally-retarded child) is probably the most frequent reason for institutionalization of the dependent person (it is noteworthy to point out that the number of Alzheimer patients is increasing steadily). The last straw is often provided by disturbed nights, uncontrolled aggression or agitation on the part of the patient, marked affective changes, uncontrolled incontinence, and illness of the caregiver.

Currently, though, the major opportunity and responsibility for pharmacists to communicate still rests on communications with patients. It needs to be understood that the massive changes in the health care system that are taking place right now and that will likely happen in the future have changed and will continue to change the "patient", from an ambulatory patient with possibly one acute disease and certain "special" patients that need a special approach (the pregnant women, mentally retarded) to an older, much more seriously ill, female ambulatory patient. Pharmacy's response to the changing nature and requirements of communications are listed in Table I. Table II lists those who most benefit from patient education efforts, and Table III lists the requirements of one "special" patient group.

TABLE 2
Who Benefits from Patient Education?

- Patients
  - with chronic diseases
  - undergoing dialysis
  - who had surgery causing psychologic impact: colostomies
  - on long-term chemotherapy
  - with any condition changing lifestyle

Who Communicates?

Clearly, the pharmacist communicates, although some studies have shown that specially trained technicians can do very useful services by relating "technical" information, such as explaining the correct use of an inhaler. Sometimes, for special patient groups, the technician may, indeed, be more effective. However, may state regulations forbid that approach.

Most important for effective communications is provider continuity. Patients who see a different pharmacist every time will not be as successful in cooperating with an established regimen as those who see the same provider all the time. One only needs to think of advertisement for the "personal banker", the "family dentist", the "family podiatrist" and many others to realize that this concept has been accepted by a wide range of health- and non-health-related professionals.

TABLE 3
A Potentially Difficult Patient
The Pregnant Woman

Life Style Changes:	Weight control, restrictions in alcohol and tobacco use. Exercise.
Possible Pregnancy Problems:	Need for information on community resources. Nausea, vomiting, etc.
Possible Drug Problems:	
a. Before Delivery:	Which drugs can influence fetus (anticoagulants, antihypertensives, etc.). Does woman need vitamins, minerals, special diets? Does woman suffer from disease that can be passed on to baby: herpes, for example.
b. After Delivery:	If mother is nursing: which drugs can pass through mother's milk into baby's circulation? If mother is not nursing: Need information on infant formulas, perhaps special formulas. What are baby's needs: vitamins, minerals, diapers, diaper rash. Caution on vomiting and diarrhea, Reye's syndrome, fever, etc.
Most At Risk:	Children having babies

What is Communicated?

A look at the major reasons for ineffective communications (Table IV) helps to identify those things that must be communicated. Clearly, that is not restricted to drug information.

First of all, information must be individualized. What information does the specific patient need? Those who give information must realize that patient status may be, and most often is, a changing status, necessitating a changing communication concept with time for that patient.

Information must be *current, complete,* and *appropriate.* For example, a newly-diagnosed hypertensive patient may need information on the specific drug, exercise, dietary restrictions, smoking and alcohol-intake restrictions, and information on duration of therapy. Since the antihypertensives are among the group of drugs identified as having a high incidence of side effects, patients need to be informed about those, too. Side effects are likely to cause 40% of patients to default completely within the first year. Thus, patients need to know the risk that uncontrolled hypertension causes, in terms of increased morbidity and mortality, which then must be balanced against a possibly decreased quality of life. Young people, in particular, are likely to default because of sexual dysfunction caused by these drugs. For elderly patients, there are still other concerns. One side effect of these drugs may be orthostatic hypotension and dizziness. Elderly are likely to take a multitude of other drugs that can have the same side effects, increasing the risk to the patient considerably. Thus, pharmacists may wish to decrease that risk by suggesting alternate drugs to the physician, but also making suggestions to the patient about safety in the home. This could include information on the need for a night light, the undesirability of a throw-rug next to the bed, and how to rise from a supine position safely.

TABLE 4
Major Reasons for Ineffectives Communications Patients

Attitudinal Factors:	Lack of motivation, poor health beliefs.
Knowledge Factors:	Unsure of purpose of desired outcome, necessary length of therapy, dosage, administration times. Lack of warnings and information on side effects.
Social Factors:	Isolation, lack of support system, difficulty in coping, lack of regular supervision.
Behavioral Factors:	Capricious non-response, "intelligent" selection of certain communicated factors.
Patient Status:	
a. Age	Pediatric, geriatric
b. Functional	Disability, physical impairment, sensory impairment (visual, auditory, tactile), dependency, literacy (inability to read or understand english language).
c. Mental	Mental impairment (anxiety, confusion, dementia, depression), post-illness asthenia.
Drug Factors:	Multiple regimens with multiple administration times, side effects, oversedation, cognitive impairment

Patients suffering from rheumatoid arthritis present with gastritis and gastric erosion more frequently than the general population. Thus, those placed on non-steroidal anti-inflammatory drugs should be cautioned against concurrent use (particularly simultaneous administration) of ascorbic acid, aspirin, potassium supplements, reserpine, and a host of other drugs, as well as coffee and alcohol.

There is still a great deal of hesitancy to counsel patients on side effects of drugs, which is understandable. In the past, it was accepted that hose with a "silent" disease need particular efforts, since the disease had no overt symptoms, and patients would likely stop the drug prematurely (infections, hypertension). It has now been shown that 40% of patients receiving non-steroidal anti-inflammatory drugs also stop taking their drugs, mainly because of the influence of their side effects. Thus, patients must understand what to expect. That also holds true for patients receiving antidepressants. Patients will notice considerable side effects almost immediately, but the therapeutic effect may be delayed two to three weeks.

In any case, before a pharmacist decides on specific counseling needs, there should be an assessment (Table V) and, in case of some special patients, notes as to future, on-going requirements (Table VI). In every case, the patient must understand what a certain regimen will do and will not do. Unreasonable expectations, both on the part of the provider and patient, most often lead to serious problems.

TABLE 5
A Guide to Assessment

Is the drug necessary?
If so, which dosage form?
Which treatment is most appropriate?
Can patient tolerate or manage an additional drug?
Should the standard adult dose be modified?
Which side effects are likely to occur?
Which drugs should be avoided, if possible?
Should special packaging be used to make drug "accessible"?
Can self-medication be achieved?
Can the medication be stopped?

TABLE 6
Maximizing Compliance

Direct	Careful Rx history
	Consider non-drug therapy
	Use only essential drugs
	Make sure regimen is appropriate
	Review regimen every 6 months
	Reduce daily number of doses
Observation	Look for mental status changes
	Look for anticholinergic effects
	Look for incontinence induced by high-potency diuretics
	Watch for drugs that can cause falls and fractures by impairing alertness, mobility, or normal cardiovascular tone and blood pressure

Source: Avorn J: As quoted in Geriatrics 1985; 40 (1):31.

How, When, Where and How Long to Communicate

Table VII shows that all efforts to communicate will fail unless they are performed with enthusiasm. Poor "non-verbal" communications play a major role in failure of communication efforts. If the patient feels that this "extra" effort is really one that is performed unwillingly (where do we find time? who pays us for this?), then the efforts are doomed to failure.

There are essentially four communication channels available: auditory, verbal, visual, and tactile, and at least two should be used concurrently. However, the pharmacist must first establish whether the patient suffers from any visual or hearing impairment or literacy impairment (can patient read and understand the language used?).

In hospitals, in waiting rooms of outpatient pharmacies, there have been used "generalized" A/V tapes for time periods when patients from specialized clinics would likely come to have their prescription filled. For example, A/V tapes would be shown which highlight dietary instructions for diabetics patients when the diabetes clinic would function. These efforts could then be reinforced by personal, individualized instructions. In general, combinations of methods should be used. If written instructions are used that are commercially available, the pharmacist should first read them, to assure that they are appropriate, understandable, and applicable. Too much material is available at reading levels that are much too high, in language that is not understandable, giving information that is not necessary.

Verbal instructions must be understood in a continuum of needs. Patients are likely to have a short attention span (three to five minutes at most), will likely remember only the first part of any instructions, and, if too much information is given, will "select out" only that information they feel is important.

Many community pharmacists have already establish a good data base on their patients. Thus, instructions regarding the management or treatment of a new disease, *in the context of an already existing regimen,* are made possible and easier. The first instructions, indeed, may be across the counter, and just touch on administration instructions (when and how). This, then, would be followed-up when refills are obtained.

Communications must be based on the assurance that the patient *can* follow instructions. A patient with Parkinsonian tremor, arthritis, and poor vision is not likely to be able to follow instructions which direct that "two drops be instilled in each eye twice a day".

TABLE 7
Major Reasons for Ineffective Communication Providers

Attitudinal:	Unenthusiastic
	Insistence on "compliance".
	"general" rather than "individual" approach.
Behavioral:	Provider discontinuity
	Non-removal of barriers
	Non-recognition of "difficult" patient or "patient-at-risk"
	Lack of use of sufficient number of communication channels (auditory, verbal, visual, tactile).
	Non-differentiation between "acute care" and "chronic care" needs.
a. Overenthusiastic:	Too much information, too much information at one time.
b. Unenthusiastic:	Insufficient information, no follow-up, insufficient response to individual patient needs, no encouragement of patient to ask questions, no assurance that patient understands and *can* and *will* follow directions

New Communication Needs

The chronic care sector is the fastest-growing sector in the current health care system. Close to 70% of all prescriptions dispensed are now for chronic care drugs. Chronic care will most likely be "medically-assisted" self care, and special requirements for this sector are outlined in Table VIII.

In this sector, in particular, OTC drugs will be used heavily, and patients must understand that OTC drugs, while found "safe and effective" individually, may well not be safe and effective in a complex therapeutic regimen. Selection of OTC drugs in general and specific OTC drugs in particular becomes extremely important (which antacids change urinary pH and which do not?) and considerable communication efforts should be developed in this area.

The need for preventive care methods must be communicated, particularly for special patients. Patients with urinary incontinence must understand the need for skin care and, if there is skin break-down, methods and medications that can be used to address this problem. Care-givers of bed-bound patients must understand the need to prevent pressure sores and materials that will help to prevent pressure sores should be recommended.

Inner-city poor, likely to live in non-air conditioned housing, need to understand that extremely high summer heat may lead to dehydration and toxic drug levels, while forced air heat in wintertime may predispose the patient to dry skin and respiratory infections. nPharmacists may then communicate the need for humidification in order to prevent these problems.

In general, patients need to understand that many problems need not be accepted stoically, but can often be related to side effects of drugs. These problems should be reported so that the pharmacist, in turn, can communicate with the physician and recommend alternate drugs. In one study in England, 65% of adverse drug effects could have been prevented by selection of an appropriate, alternate drug.

TABLE 8
Improving Medically-Assisted Long-Term Self-Care

1. Establish partnership-like relation and trust
2. Direct efforts toward enabling factors and good information base
3. Use Cues
    a. Tailor drug administration to activities of daily living
4. Use reminders
    a. Stress importance of medically-assisted self-care at every visit
5. Follow-up
    a. Call if appointment or drug refill is missed.
    b. Vary number of contacts directly with degree of cooperation
    c. Stress need for feedback
6. Use rewards
    a. Recognize patient effort, progress
7. Achieve social support
    a. Involve family caregiver

Communication Aids

A host of communication aids are available, some proven, many unproven and too expensive. The Office of Technology Assessment of the US Congress foresees the day that computers will link patients with providers, but that day seems far off. Counseling booths have been used in hospitals (University of Maryland) and community pharmacies (Peoples Drug) to provide a measure of privacy (extremely important for young customers seeking counseling on contraceptive devices). A plethora of "pre-cooked" written instructions is available, which is not too helpful for the "individualized" approach, although the leaflets issued by AARP have been found effective, probably because they address many concerns, such as size and type of printing, limiting the amount of information to the most important, and special patient concerns.

Special packaging, such as that marketed by MSI not only supports good communication, but is informative in itself, and helps in audit, management and administration of the medication.

Development of a variety of "memory-enhancers" is available that "beep" when a medication should be taken. These are still expensive and probably only applicable and helpful to patients receiving only one drug.

Auxiliary labels should continue to be used, but much more selective than they are being used in some instances. Addition of four or five auxiliary labels to the labeling of a small vial serves only to confuse the patient, rather than help. It is regrettable that clear glass vials of different shapes are no longer available, since they helped the patient identify drugs and could be used by visually-impaired patients who would identify different drugs by differently-shaped containers.

The most basic and most important aids, though, are a complete, extensive, and always updated *patient record* available to the pharmacist and a complete *medication record* in the patient's hands, one that will list all Rx drugs, all OTC drugs, plus all agents a patient may purchase in the health-food store.

Suggested Aids to the Provider

Can a pharmacist or a pharmacy meet all of the outlined requirements? Of course not. It is clear that a "selective" process ought to be used, a "risk" identification. What are the drugs most often involved in serious problems? According to studies these are the nonsteroidal anti-inflammatory drugs, the antihypertensives, the anticholinergic anti-Parkinson drugs, digitalis, and the psychotropic drugs. Thus, patients receiving these drugs merit special attention.

Who are other patients that merit special attention? Those with multiple pathology, receiving multiple drugs rank high. Those with sensory, physical and mental impairment rank high. The pediatric patient and the geriatric patient fall into the "risk" category, as do those who live alone and have no social or family support. The pharmacist will want to pay special attention to pregnant women and the diabetic patient, indeed any patient afflicted with a disease that is hard to stabilize and that is likely to change frequently. Pursuance of this approach will be most helpful to most patients at highest risk.

Some "Do's" and "Dont's"

1. Health care providers' feelings towards the pa-

tient are conveyed even without words. If provider expresses little concern, patient is less likely to adhere to regimen.
2. "Difficult" patients may not be difficult at all, but patient's behavior may be a cover for fear of an illness.
3. Remember that many patient complaints may be connected to fear, anxiety and family problems, that both provider and patient are reluctant to discuss. This can lead to treatment of symptoms, not underlying problem.
4. Do not use jargon. Medical jargon is equivalent to bad handwriting. Who knows that "lymphatic hypertrophy" means "swollen glands"?
5. Diagnosis and treatment may be clear, but effort fails when life-style changes are required but not explained clearly.
6. Patients who need to make life-style changes can easily become frustrated.
7. Remember: some patients like a "authoritarian" approach. Others like an "educational" approach, and still others a "mutual cooperation;" approach. Which one does your patient like?
8. Remember: patients may not seek clarification, may acquiesce and may appear to agree, while thinking "Not Me"!
9. Skeptical, unconvinced or dissatisfied patients may turn to self-diagnosis and self-treatment.
10. Set reasonable short-term goals. Approach long-term goals in stages.

Possible Barriers to Communications with Older Adults

1. It is difficult to talk to older adults about aging and the effects of aging.
2. Older adults want us to listen, hear, care, and respond. They often complain that nobody is "listening". The necessary balance between talking (sending the message) and listening (assuring oneself that the message has been received and understood) is more difficult to achieve with older adults.
3. Older adults may have diminished ability to understand speech and other sounds.
4. The wrong vocabulary will block good communications. Professional and scientific language, used in communicating with any consumer but particularly with older adults, is a major barrier. Scientific or professional language is the equivalent of bad handwriting.
5. It is difficult to overcome social and health behavior that is negatively influenced by social isolation of the consumer.
6. The elderly may adhere to values learned and accepted in their younger years. Younger adults, communicating with them, may have different beliefs and value systems.
7. The provider must overcome the "generally accepted" dictum that you cannot teach older persons anything new, and that a change in health behavior in older age will be of no benefit anymore.
8. The older adult's short-term memory and recall, as well as learning speed (but not learning ability) may be diminished, and therefore
9. The older adult's attention span can easily be exceeded.
10. Sensory losses or decrements in older adults may be devastating to them and may well prevent good communications:
    a. Auditory loss, of which probably more than one-half of all elderly suffer to different degrees of severity, can be a major barrier to direct communications. Indirectly, auditory loss can lead to very defensive behavior on the part of the consumer and a loss of "trust". Otosclerosis, stroke, mastoiditis, otitis media, nerve damage resulting from the administration of a variety of drugs may have caused or may cause significant auditory decrements in the elderly.
    b. Vision loss: Good sight is essential for identifying medications and taking them correctly according to instructions which are, unfortunately, most often written in small letters on background that intereferes with better reception. Probably more than one-half of the elderly suffer from vision impairment, due to such diseases and disabilities as cataracts, glucoma, dry eye, and others. Primary aging, itself, is most often responsible for lessened acuity.
11. Physical limitations and mobility problems, such as arthritis, may be enormous barriers to good communications and follow-through. For example, serious arthritis and hearing loss may prevent an older consumer, homebound or bedbound, from communicating effectively by telephone, often the only available means of communication. Arthritis, tremor, and poor eyesight may make it impossible for an older adult to follow directions in administering eye drops.

Once pharmacy practitioners have learned about these potential barriers and have dealt with them appropriately, they need to devise a system or systems to address the large number of elderly which will demand services from them in the near future.

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Tie one on.

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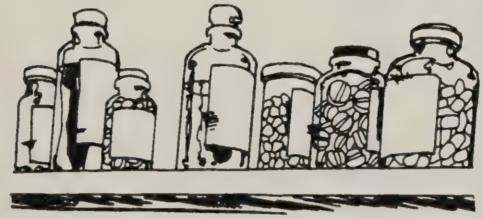
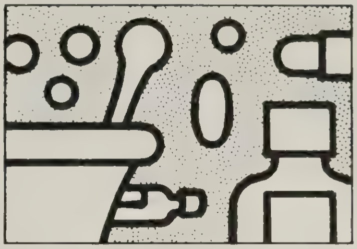


Things You Should Know FOR YOUR GOOD HEALTH



November Is National Diabetes Month

Diabetes is the leading cause of blindness in the United States and is the third leading cause of death by disease. More than one-half of all heart attacks and two-thirds of all strokes occur in diabetics.

Diabetes is a disease that affects the way the body metabolizes carbohydrates, fats and proteins. There is no known cure for diabetes and it is found to be hereditary. In the United States one family in four is affected by it. It is the second leading cause of the inability to have children.

Diabetes is classified in several ways. The two major types are: **Juvenile Onset** and **Maturity or Adult Onset**. These types of diabetes are different from each other and each has its own characteristics.

Juvenile Onset diabetes occurs during youth, usually before age 25. Only five per cent of all diabetics have this type. The person afflicted with this type is lean and dependent on insulin because the pancreas, the gland which produces insulin, ceases to function properly. Insulin is necessary to properly utilize glucose, a sugar which supplies the body's energy. As a result, a surplus of glucose accumulates in the blood and spills over into the urine. The only treatment for this type of diabetes is the injection of insulin and adherence to a very strict diet. The average insulin dependent diabetic spends nearly $1,000 per year on disease-related medication.

Maturity or Adult Onset diabetes usually occurs after the age of 40. Approximately 80 per cent of diabetics are of this type. Most maturity onset diabetics are overweight. In many cases, insulin and oral antidiabetic medication may not be needed. The loss of weight and a well-balanced diet may be sufficient to control the disease. Although, in severe cases, insulin injections may be required to help control the blood glucose levels.

Oral antidiabetic medicines may be used in the maturity onset diabetic, whereas only insulin can be used in the juvenile type. All diabetics must adhere to a well-balanced diet in order to control the disease properly, although the majority of maturity onset diabetics can be managed by diet alone.

WARNING SIGNS OF DIABETES!

Juvenile Onset diabetes is characterized by the sudden appearance of:

Constant urination
Abnormal thirst
Unusual hunger
The rapid loss of weight
Irritability
Obvious weakness and fatigue
Nausea and vomiting.

Any one of these signs can mean diabetes. Children usually exhibit dramatic and sudden symptoms and must receive prompt medical treatment.

Maturity Onset diabetes may include any of the signs of juvenile diabetes or:

Drowsiness
Itching
A family history of diabetes
Blurred vision
Excessive weight
Tingling, numbness in feet
Easy fatigue
Skin infections and slow healing

Many adults may have diabetes with none of these symptoms. The disease is often discovered during routine physical examinations.

State Pharmaceutical
© Editorial Association

Pictured below is a reproduction of the front and back sides of a leaflet prepared for distribution by community Pharmacists to their patients. It is specifically designed to explain to the consumer the vital economic issues threatening community Pharmacy. Remove this page, cut this explanation copy off, and fold the leaflet in two so the copy is centered on both sides. Take it to your local "quick" printer for reproduction in the quantities necessary or use a copying machine. Bright color stock can attract attention. Be prepared to discuss these vital economic issues with your patients.

Don't Let Them Tell You Where To Go!

There are many new health insurance programs available today. Many of these involve innovative features designed to improve the health care you receive. But many also contain a rather unwelcome feature. Unlike traditional health insurance, these new plans, such as Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs) often take away your freedom of choice in selecting the health professionals, hospitals, and pharmacies where you are permitted to obtain care. Sometimes you are given the option of going to the physician or pharmacy of your choice, but only at an increased out-of-pocket cost to you. Many patients discover too late that their new health coverage doesn't permit them to continue having their prescriptions filled at the pharmacy of their choice. Often they must go to a pharmacy that is less conveniently located, or that may have less convenient hours, or may not offer the range of services that is desired.

It is important that you consider these factors when you make your decisions regarding the type of health coverage you will obtain:

- Know the specifics of the plans you are considering.
- Understand what options you may or may not have regarding the selection of the pharmacy (or doctor or hospital).
- Consider the importance of service, convenience, and confidence in the selection of a pharmacy.

There's Another ℞ That's Not For You

It's only human nature. You like to save a few dollars when you shop, don't you? After all, who doesn't like a bargain? But when you buy prescription drugs by mail do you really want to bargain away your health?

Mail order drug programs are another instance of someone telling you where to go! Mail order prescription drugs may mean cheap drugs, but when you buy by mail here's what you're missing:

- Personalized service from the "drug expert" — your pharmacist — who knows which other drugs you may be taking that would interact dangerously with your new prescription and whether you might be allergic to the new medication.
- Your own "consultant," right there in the pharmacy to answer your questions about this medication and other non-prescription items you may want to use.
- Access to your pharmacist, in an emergency or on a 24-hour basis or even at home when you can't get to the pharmacy because of illness.

The next time your health plan describes the "benefits" of mail order prescription drugs, ask yourself these questions:

- What do you do until the medicine arrives in the mail?
- What do you do if the medicine is lost?
- What do you do if the medicine is stolen?
- Is your medicine safe from temperature extremes and other dangers while on its way to you?
- What do you do when the medicine you take runs out? How long will it be before you can be resupplied?
- Do you really want to receive larger than normal quantities of a medicine, which can lead to abuse and waste?
- Do you really deserve fourth-class health care?

Let's face it: Your pharmacist knows you — the nature of your health problem and why you're taking certain drugs to help solve that problem. He or she knows this because a patient profile is kept on persons like you who desire quality pharmacy services. Your pharmacist also knows you, because he or she is right there in your hometown, an important part of the business and professional community serving you and your family. The mail order prescription drug business doesn't know you or your special needs, the way your pharmacist does.

Do you really want to give all this up — the quality of your health care — to save a few dollars?

Think about it for a minute.

We believe you'll agree: Mail order prescription drugs are no bargain.

This message is from your community pharmacist and the Maryland Pharmacists Association . . . We're concerned.

Nicholas C. Lykos, (left) MPhA Treasurer, won a free trip to London from the Schering Corporation in a sweepstakes contest. Magdalena Neumann (right) from Schering and Dale Smeltzer, a Lykos Pharmacy customer, were present.

Zenith Labs set up a Wholesaler Advisory Board. They are: (from left to right, front row) George Howerton, Vice President, Charles Leich & Company, Richard Levin, Vice President, District Wholesale Drug Company, Frank "Bud" Green, Vice President, Behrens, Inc. David Cross, Vice President of Operations for Clarksburg Drug Company—(left to right back row) Pete Mills, Manager of Sales for South Bend Drug Company, Douglas Batezel, Merchandise Manager, Bergen Brunswig Drug Company, Phil Blick, Senior Vice President, Sales for Zenith, Leslie Killebrew (sitting) Vice President Operations, Mississippi Drug Company, Edward Thwaite (sitting) Vice President, Marketing, Zenith, Robert J. Watz, National Manager, Wholesale Accounts, Zenith, James O. Leonard, President and CEO Zenith, Ted Pilch, Director Retail Marketing, Harris Wholesale Company.

Board of Pharmacy members and staff hold a goodbye party for departing members. At the Party were: (seated left to right) Attorney Ron Gass, Commissioner Milton Moskowitz, Executive Director Rosalyn Scheer, out-going Consumer member Estelle Cohen (see article on page 16), out-going President Bernard Lachman, staff member Pat Cockrell, Consumer member William Adams; (standing left to right) Commissioner Steve Cohen, Consumer member Ted Litwin, Commissioner Ralph Small, out-going Commissioner Bob Snyder, Staff member Dee Moore, Commissioner Len DeMino, President Tony Padussis and Secretary Paul Freiman.

Ms. Angela DeVaux has been newly assigned to the Baltimore territory to represent Abbott Labs. Angela has a B.S. in Business Administration from Morgan State University.

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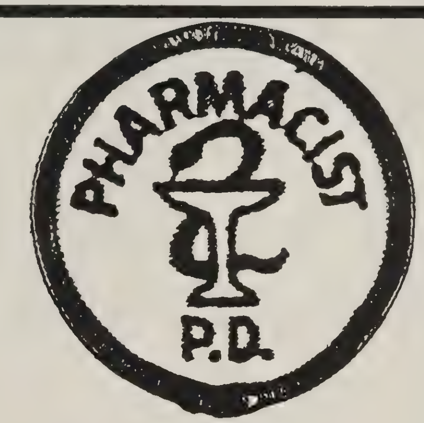
calendar

- Sept. 28–Oct. 2—NARD Convention, Louisville, KY
- Oct. 9—MSHP monthly meeting—Un. of Maryland
- Oct. 19—Alumni Assn. Dinner Meeting
- Oct. 21–25—MPhA Trip to Scottsdale Arizona
- Nov. 21–22—School of Pharmacy Seminar—"The Cocaine Epidemic"
- Jan. 14–25—MPhA Trip to Hawaii
- Jun. 16–18—MPhA/Alumni Assn. Ski Weekend at Hunter Mountain
- Mar. 8—BMPA Annual Dinner Dance
- Mar. 28–Aprl. 1—APhA Convention, Chicago, IL
- June 21–25—MPhA Annual Convention, Ocean City

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.



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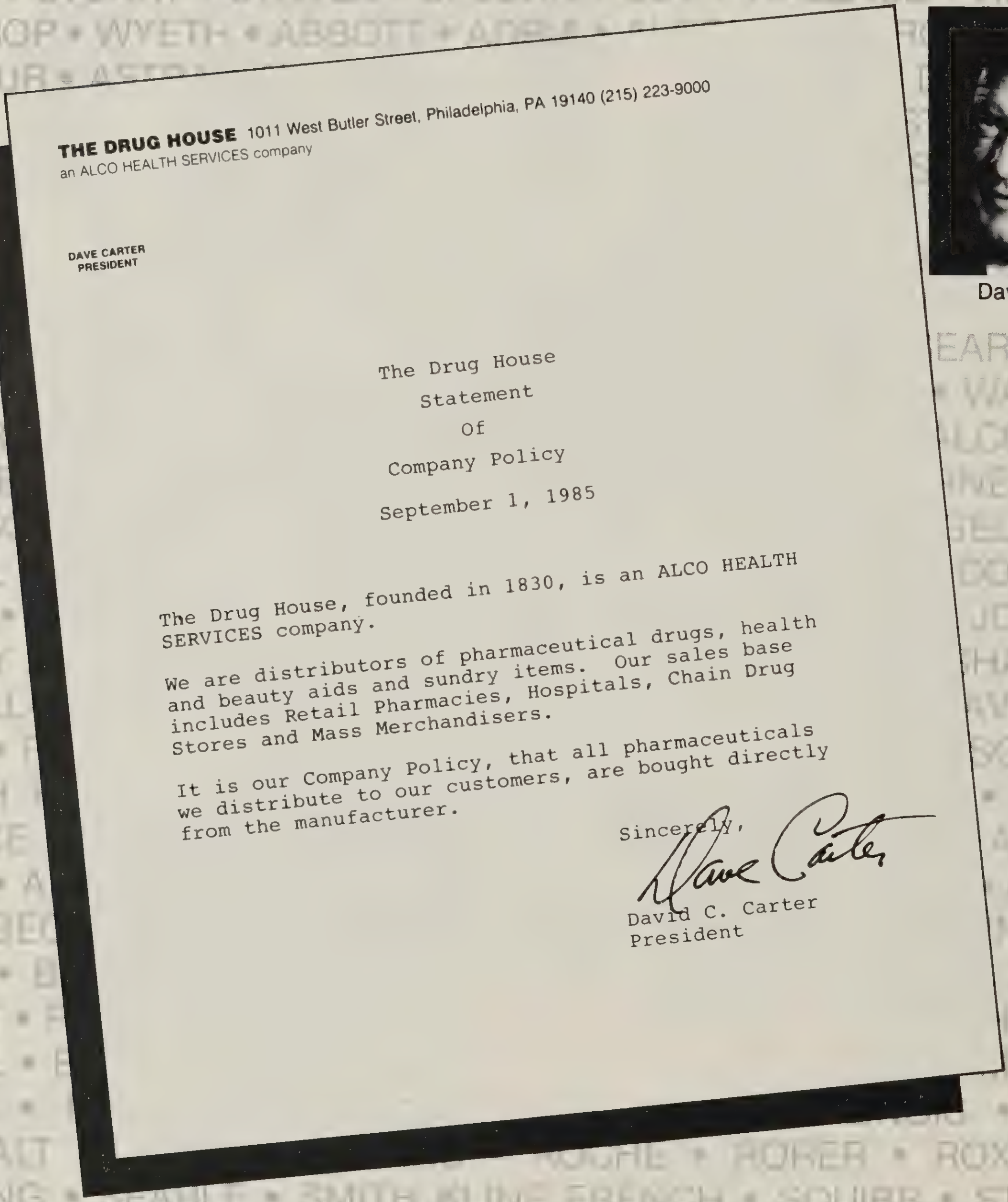

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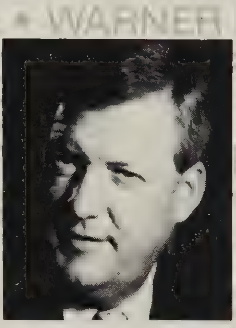

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THE
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PHARMACIST
Official Journal of
The Maryland
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November 1986
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No. 11

Advising Consumers on OTC Cold Remedies

— Thomas A. Gossel
— J. Richard Wuest

History of the Baltimore Veteran Druggists' Association

— B. F. Allen

Pharmacy Achievement Scholarship Application

Calcium Use in an Ambulatory, Community-Living Population

— Joy Williams
— Madeline Feinberg
— Peter Lamy

THE MARYLAND PHARMACIST

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TELEPHONE 301/727-0746

NOVEMBER 1986 VOL. 62 NO. 11

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ONE NIGHT I DREAMED:

- The new tax reform bill exempts pharmacists from paying any federal income tax.
- The Post Office issues an edict making it illegal to send drugs of any type through the U.S. mail. It was found the effective dates expired before delivery.
- Scientists discover that the presence of corn, potatoes, and onions adulterates prescription drugs, making it mandatory to remove all medicines from grocery stores.
- The State announces millions of dollars in surplus funds in the Medical Assistance Program and awards the excess monies to participating pharmacies.
- In the interest of fair play, HMO's agree to operate under the same restrictions as community pharmacies and relinquish any special consideration currently enjoyed; i.e., purchasing power.
- Hospitals plead with pharmaceutical manufacturers to offer all community pharmacies hospital prices on all prescription items.
- Pharmaceutical manufacturers, seeing the error of their ways, award millions of dollars to community pharmacies for past overcharges.

George C. Voxakis
PRESIDENT

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 10

Advising Consumers on OTC Cold Remedies

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. review the etiology, course of events, and symptoms associated with the common cold;
2. discuss current trends in treating symptoms of the common cold with OTC products.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Objectives

At the conclusion of this lesson, the participant will be able to:

1. discuss specific pathogens, viral and bacterial, known to cause the common cold;
2. list the ingredients of OTC products specifically intended to treat cold symptoms, and state their pharmacologic actions;
3. differentiate a cold from influenza, based on reported symptoms; and
4. demonstrate the ability to choose important advice to give consumers purchasing an OTC cold remedy.

Introduction

Americans reportedly suffer from common colds more frequently than from any other ailment. It is estimated that they experience over 500 million colds per year.

Pharmacists are often called upon to provide information and answer questions about this malady, as well as recommend OTC remedies to treat its various symptoms (see Table 1).

TABLE 1

Sales Volume For OTC Cough/Cold Remedies In Millions of Dollars

Remedies	**$ (millions)**
Cough/Cold Tablets and Capsules	569
Cough/Cold Remedies	371
Cough Drops/Lozenges	210
Nasal Sprays	111
Allergy/Hay Fever and Asthma Products	108
Sinus Remedies	70
Topical Ointments	46
Nose Drops	27
Room Sprays	11

Adapted from: *Drug Topics*, July, 1984

While there is not yet a cure for the common cold, considerable research has been conducted and new data are constantly published. Many of the "tried and true" remedies of years past are effective, while others have been shown to be irrational, ineffective, and, in some cases, potentially toxic.

This article reviews current knowledge concerning the etiology of the common cold. The findings of the FDA/OTC advisory panel on self-treatment of cold symptoms will be discussed. Also, the distinction between colds and influenza, another common respiratory ailment, will be made. Consumer counseling for adults and children will be presented.

The Common Cold

Generally, as people age, they experience fewer colds. Pre-schoolers develop 6 to 12 colds per year on the average, and school-aged children experience approximately 6 colds yearly. By age 40, the number declines to 1.7; by age 60, to 1.3 colds per year. This decline can be explained by understanding the body's immunological system.

Since colds are viral-induced, the body needs time to develop its immunological defenses against these viruses. With time, the immunologic system is usually able to stop the progression of a cold infection before it develops into a full-blown syndrome.

It is sometimes difficult to differentiate cold symptoms from other respiratory tract infections. For example, persons over the age of 60 experience many respiratory tract infections that resemble the common cold. Many of these afflictions are related to allergy or to bacterial or other infections of the respiratory tract. Therefore, it is difficult to determine whether the individual will respond to OTC medications.

Under the age of 3, boys develop colds more frequently than girls. After that, the ratio changes in favor of the girls. This may be due to the fact that females, as young mothers, spend more time with their youngsters than fathers. Women are, therefore, exposed to more cold viruses because of the many colds children develop and because colds are highly contagious.

While the common cold may occur during any season, there are three primary periods in which colds predominate: early autumn following the re-opening of school, shortly after mid-winter, and early spring. The first season is related to the large numbers of children coming together and interacting after being separated for several months. The latter two seasons are related to fluctuating environmental temperatures.

Interestingly, the incidence of colds is not increased by damp, chilly weather. Individuals residing in large urban areas typically experience a greater number of respiratory illnesses than their counterparts from more rural areas.

Cold Viruses

More than 125 viruses have been identified as causes of the common cold. The major group is the *rhinoviruses*, of which over 75 are known to be pathogenically important. Other viruses include the *adenoviruses*, *coxsackieviruses* and *echoviruses*. These, plus other viruses, are responsible for over 95 percent of all colds.

Cold viruses, like other viruses, are composed of a single strand of ribonucleic acid (RNA) which is surrounded by a protein/lipid shell. The invading virus first binds to susceptible cells, then penetrates inwardly. Within 4 to 5 hours of entry, the virus commandeers the cells' genetic coding system, and replicates their own RNA strands rather than those of the host. Within 16 to 18 hours of infection, protein components of the virus also replicate. By this time, completely duplicated virus can be detected within the cell. The cell then bursts, releasing virus into the surrounding area. Contagious cells are contaminated and the process repeats resulting in further viral replication and cell destruction. Meanwhile, histamine and the other chemical mediators of inflammation are released from the disrupted cells, and various symptoms of the common cold appear.

Cold viruses are extremely contagious. Although they are readily acquired by inhaling airborne particles, the major spread of colds is now believed to be due to touching contaminated objects such as doorknobs, telephones, or the affected person himself. Once the virus is on the hands, touching the eye or nose, or other mucous membrane results in autoinnoculation.

Cold viruses are reported to retain virility for several hours when left on inanimate objects. Obviously, pharmacists are at high risk of developing colds from viruses brought into the pharmacy by affected patients.

Colds not directly related to viral contamination are caused by bacterial invasion. The most commonly encountered bacterial species include the streptococci such as *S. pyogenes*. A bacterial cause should be suspected whenever symptoms persist beyond 7 to 10 days of onset. Fever, if present, should recede within 3 to 4 days. Whenever symptoms last longer than these periods, medical attention should be sought.

A number of respiratory afflictions induce symptoms similar to those of the common cold. These include influenza, allergic rhinitis, and streptococcal pharyngitis. It may be difficult to distinguish between causes of symptoms, especially those produced by influenza.

Table 2 differentiates cold and flu symptoms. Allergic rhinitis ("summer cold") is seasonal and related to certain plant growing periods. Streptococcal pharyngitis ("strep throat") is associated with sore, swollen lymph nodes in the neck, and an extremely sore throat.

Treatment of the Common Cold

There is a wide variety of OTC products intended to treat cold symptoms. While the common cold is the most prevalent of all illnesses, there is no known method to prevent or cure it. Rather, treatment is intended to alleviate sypmtoms until the body's defense mechanisms can restore the patient to normal health. These remedies contain ingredients intended to treat specific symptoms noted in Table 3.

Pharmacists should determine which specific symptoms are present before recommending a product which contains only those ingredients which are actually indicated. The old-time "shotgun" approach to treating the common cold is no longer considered effective therapeutics because it exposes the patient to unnecessary side effects.

Analgesics/Antipyretics. Aspirin, acetaminophen, and most recently, ibuprofen, are effective analgesic/antipyretic medications used to treat aches, pains, and fever associated with the common cold. Aspirin and acetaminophen are qualitatively and quantitatively similar.

Ibuprofen is qualitatively similar to the others; some studies have shown that it is quantitatively superior. A 200 mg dose of ibuprofen provides equivalent pain/fever relief as 650 mg of aspirin or acetaminophen.

TABLE 2

Is It A Cold Or The Flu?

Symptoms	Cold	Flu
Fever	Rare	Characteristic; high (102-104°F); sudden onset; lasts 3-4 days.
Headache	Rare	Prominent
General aches & pains	Slight	Usual; often quite severe.
Fatigue & weakness	Quite mild	Extreme; can last up to 2-3 weeks.
Prostration	Never	Early & prominent.
Runny, stuffy nose	Common	Sometimes
Sneezing	Usual	Sometimes
Sore throat	Common	Sometimes
Chest discomfort, cough	Mild to moderate; hacking cough.	Common; can become severe

TABLE 3

Eight Basic Symptoms Associated With the Common Cold

	Treatment
1. Cough	C
2. Fever	A
3. Headache	A
4. Itchy, watery eyes	B
5. Muscle aches & pains	A
6. Nasal congestion	D
7. Runny nose	B
8. Sore throat	A, E

The above can be alleviated by:
A. Analgesics
B. Antihistamines
C. Antitussives
D. Decongestants
E. Local Anesthetics

The use of these drugs to provide relief of aches and pains associated with the common cold is not associated with known therapeutic problems. However, there is some controversy regarding whether or not a fever, which is at least partly responsible for the aches and pains, should be resolved.

Fever is one of the body's normal defense mechanisms. Virus multiplies maximally at a normal body temperature. Whenever this increases, viral replication is checked. There is rarely medical significance resulting from a temporary increase of a few degrees of body temperature.

On the other hand, feverishness contributes to muscular aches and pains and the general discomfort of the common cold. Barring other contraindicating factors, there is little reason for a cold sufferer to avoid taking an analgesic/antipyretic. But whenever the temperature persists or worsens, the individual should seek medical attention.

Reye's Syndrome, a rapidly developing course of hepatic failure and encephalopathy, has been linked with the use of aspirin in children experiencing the onset of flu-like symptoms. Although there is much controversy surrounding the findings, it is recommended that aspirin not be given to children when an influenza infection is suspected. Reye's Syndrome has a 30 percent mortality rate.

Decongestants. Decongestants provide the basis for relief of symptoms of stuffy nose and respiratory congestion. Pharmacologically, they are sympathomimetic amines which reverse vasodilation brought about by histamine and other chemicals which cause nasal stuffiness. Because the vasodilation of vessels within the nasal mucosa reduces the size of air passages, vasoconstriction can reduce exudation of fluid into the nasal area. They also help alleviate symptoms of runny nose.

Decongestants may be applied topically or taken orally. Orally ingested, systemic products are promoted to provide decongestant action throughout all parts of the nasal pharyngeal and sinus mucosal areas. Systemic drugs require a longer period to act because they must dissociate from their oral dosage forms before being absorbed into the blood. However, their action is claimed to be more prolonged compared to topical decongestant dosage forms. Also, systemic medications may produce systemic effects which are rare following use of topical decongestants when they are used correctly.

Topical decongestants provide prompt vasoconstriction of only those tissues upon which they are applied. When excessive topical solution is placed in the nose, it may drain into the stomach, and eventually be absorbed.

TABLE 4

Safe and Effective Nasal Decongestants For OTC Use

Decongestant/Dose or Conc.	Form
Ephedrine preparations (hydrochloride, sulfate); Racephedrine hydrochloride, l-deoxyephedrine, 0.5%	Topical
Naphazoline hydrochloride, 0.025-0.05%	Topical
Oxymetazoline hydrochloride, 0.025-0.05%	Topical
Phenylephrine hydrochloride, 0.125-1.0%	Topical
Phenylpropanolamine preparations (bitartrate, hydrochloride, maleate), 6.25-25 mg (SA 75mg)	Oral
Propylhexedrine, deliver 0.4-0.5 mg in each inspired breath	Topical
Pseudoephedrine preparations (hydrochloride, sulfate), 30-60 mg (SA 120 mg)	Oral
Xylometazoline hydrochloride, 0.05-0.1%	Topical

The ingredients listed in Table 4 have been shown by the FDA/OTC advisory panel to be safe and effective for self-medication of nasal congestion. OTC products containing these ingredients can be assuredly recommended for this use.

Antihistamines. Antihistamines are often included in OTC cold products. However, they are not generally effective in alleviating symptoms of the common cold except for rhinitis, lacrimation (watery eyes), and sneezing.

To be maximally effective, antihistamines must be taken prior to onset of histamine-induced inflammatory reactions. Therefore, patients taking antihistamine-containing products for relief of symptoms listed above should be instructed to take the medication at the first appearance of cold symptoms.

Antihistamines possess anticholinergic activity. Reported benefit from antihistamines may be related at least partially to this activity. The FDA/OTC advisory panel that reviewed anticholinergic drugs *per se* did not approve any of these ingredients for Category I (safe and effective for OTC use) status for OTC cold remedy products.

Anticholinergics are not considered to be safe for self-use in doses that are effective. Most manufacturers of OTC cold remedies have already removed anticholinergic ingredients from their products; others will do so soon. Because antihistamines have anticholinergic activity, patients for whom anticholinergic drugs would normally be contraindicated (i.e., persons with an inflammed prostate, glaucoma, or asthma) should not take products containing antihistamines without first checking with a doctor.

Antitussives/Expectorants. Productive and non-productive coughing are symptoms of the common cold. Both have individual characteristics, different pathology, and are treated differently.

Fads. A fad is an unproven event postulated to achieve a goal that is accepted with enthusiastic zeal. Fads come and go. Preventing and/or treating the common cold with megadoses of Vitamin C was a fad that persisted for more than a decade.

The use of **zinc gluconate** lozenges is a new fad in the treatment of the common cold. A limited number of reports that have appeared in the medical literature over the past several years have shown that zinc seems to inhibit replication of upper respiratory tract viruses. This allows the body's normal defense mechanisms to rid the body of these pathogens.

Specifically, cold symptoms are reportedly checked when a zinc gluconate tablet or lozenge is dissolved in the mouth every hour for up to four doses. Dosing must begin at the first appearance of symptoms.

Other supposedly acceptable forms of zinc include the aspartate and ascorbate salts. Zinc is released into the mouth and absorbed across the oral mucosa where it reaches tissues and blood levels in the upper respiratory tract.

Although the philosophy of the zinc fad has some pharmacological merit, there is little current evidence that it actually causes relief of symptoms. However, this therapy is not harmful. Pharmacists should instruct consumers to discontinue treatment if symptoms worsen or persist after the specified self-medicating period.

Consumer Advice

The common cold is among the most common of all human diseases. But there are no effective methods to either prevent or cure it. Available treatments are directed toward alleviating the following symptoms: headache, muscle ache, nasal congestion, postnasal drip, sneezing, cough, watery eyes, and occasionally fever. These symptoms are checked until the body's natural defense mechanisms can restore the patient to normal health.

Symptoms that occur more often than normal or persist longer than 7 to 10 days, 3 days for fever, may signal the presence of a disease state other than the common cold. The pharmacist should question the patient in an attempt to rule out other causes.

Drug Interactions. Pharmacists should be alerted to potential drug interactions that may result when OTC cold medications are taken. A potentially dangerous interaction exists between sympathomimetic amines and monamine oxidase inhibitors (e.g., Eutonyl, Marplan). The later can severely potentiate the former's action leading to hypertensive crisis and even death. Concurrent use is contraindicated. A warning to this effect appears on the labeling of OTC *systemic* decongestants and in the professional labeling of MAO inhibitors. *Topical* decongestants can be used safely with MAO inhibitors.

Antihistamines can potentiate other CNS depressants including alcohol. Individuals taking antihistamines should be especially careful when driving or drinking alcoholic beverages. Antihistamines can exert additive anticholinergic effects with other drugs of this category. Monoamine oxidase inhibitors can prolong and intensify both the CNS depressant and anticholinergic effects of antihistamines.

Humidity. Respiratory infections are intensified in dry environments. Symptoms such as coughing and nasal congestion will be more intense. Pharmacists should urge individuals with recurrent upper respiratory tract infections to purchase and use a vaporizer or humidifier.

Cold sufferers should be reminded to eat well and get plenty of sleep. Good nutrition and adequate rest help the body's defense mechanisms to shorten the course of an infection. Drinking 8 or more glassfuls of liquid each day will keep respiratory mucous membranes moist. These measures should hasten resolution of symptoms.

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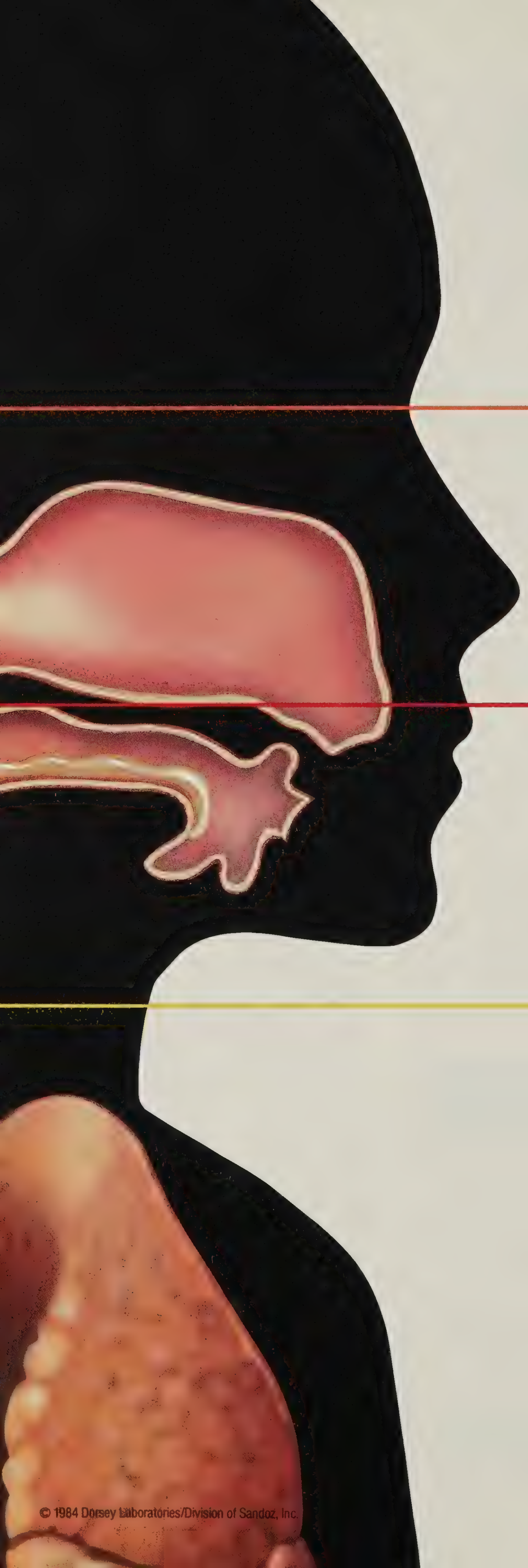
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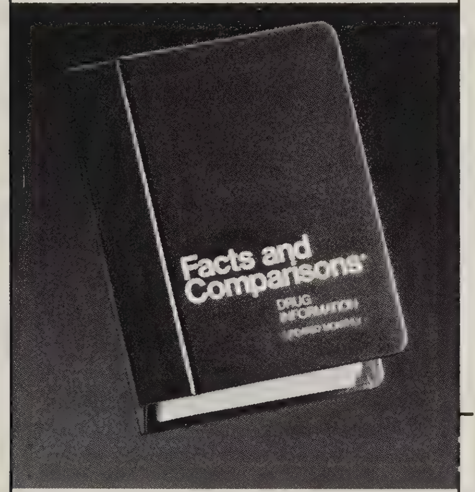

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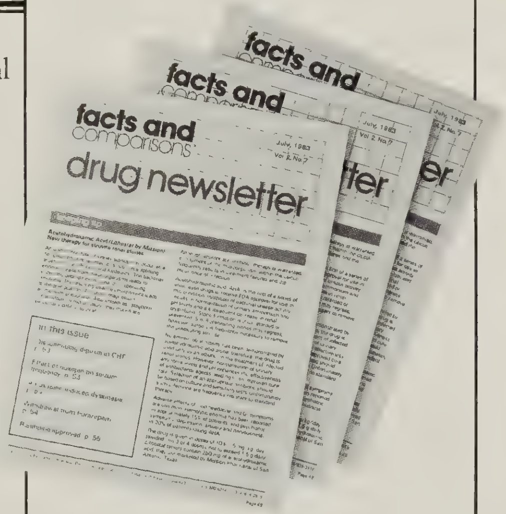

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History of The Baltimore Veteran Druggists' Association 60th Anniversary

By B. F. ALLEN, Ph.D
Retired Associate Professor of Pharmacy
University of Maryland, School of Pharmacy

On September 10, 1926, the following met at the Hotel Rennert* for the purpose of attending a luncheon and discussing the organization of a Veteran Druggists' Association in the City of Baltimore: E. G. Eberle, editor of the American Pharmaceutical Association Journal; E. F. Kelly, secretary of the American Pharmaceutical Association (offices of the Association and Journal were located at this time in Baltimore at 10 West Chase Street); Samuel Y. Harris, president of the Maryland Pharmaceutical Association and proprietor of a drugstore at the southwest corner of Lombard and Poppleton Streets; Charles L. Meyer, proprietor of a drugstore at Madison Avenue and McMechen Street, and delegate from the MPhA to the APhA and NARD conventions; Charles Neal, chairman of executive committee MPhA and associated with the Sharp and Dohme Company (southwest corner Howard and Pratt Streets); R. E. L. Williamson, president of the Baltimore Retail Druggists Association and connected with the Calvert Drug Company; Alfred Dohme, president of Sharp and Dohme; John B. Thomas, president of the Thomas and Thompson Company, wholesale and retail druggists, southeast corner Baltimore and Light Streets; William M. Fouch, proprietor of a drugstore at the southwest corner of Charles Street and North Avenue, and one of the incorporators of the Calvert Drug Company; David R. Millard, one of the founders of the Morgan and Millard drugstore at the southeast corner of Baltimore and South Streets (believed to be one of the first local all-night pharmacies); George Bunting, inventor of world-famous Noxzema Cream and founder of the Noxzema Chemical Company (now known as the Noxell Corporation); and A. G. DuMez, Dean of the School of Pharmacy University of Maryland.

The following were also invited to the organization meeting, but could not be present because of various engagements: H. A. B. Dunning, president of Hynson, Wescott and Dunning (first manufacturing firm to produce merbromin (Mercurochrome); Robert L. Swain, secretary of the Maryland Board of Pharmacy and Deputy Food and Drug Commissioner; and J. Fuller Frames, president of the Maryland Board of Pharmacy and proprietor of a drugstore at Gay and Aisquith Streets.

After partaking of luncheon, a business session was held. It was moved and carried, that there be organized a Veteran Druggists' Association in the City of Baltimore. The following temporary officers were elected: Williamson, president; DuMez, secretary; and Neal, treasurer.

The temporary president appointed a committee of five (Kelly, Dohme, Eberle, Bunting and DuMez) to draw up the details of organization for presentation at the next meeting.

With the view of facilitating the work of this committee, the following suggestions were offered: (1) meetings should be held monthly, (2) the membership should be limited to twenty-five, (3) to be eligible for membership twenty-five years in pharmacy should be required, (4) the dues should not be over five dollars per annum, (5) persons not attending four consecutive meetings without a legitimate excuse should be dropped from membership, (6) meeting should be held from 12:30 to 2:00 p.m. The length of time of meetings might be shortened, but it should not be longer than one hour and thirty minutes, (7) a suitable place for holding the meeting should be selected, (8) Wednesday would probably be the best day of the week for holding the meetings, (9) an emblem or flower should be selected (a pair of B.V.D.'s was suggested as a suitable emblem by Meyer).

It was moved and carried that Wilhelm Bodemann, also known as William Bodeman, be elected an honorary member of the Association and that Mr. Bodemann be notified by telegram of the organization of the Baltimore Association and of his election. It was also decided that Bodeman be invited to attend the first stated meeting as a guest of the Association.

The first Veteran Druggists' Association was organized in Chicago in 1898, by the pharmacist Thomas Nevin Jamieson. After World War I, under the influence of William Bodeman of Chicago, the idea of associations of "veteran" (older) pharmacists spread and strong groups existed not only in Chicago, but also in Milwaukee, Minneapolis, Twin Cities, St. Louis, New York (1923), and the District of Columbia (1925).

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* Once one of the city's most elegant hotels, the Rennert stood at the southeast corner of Liberty and Saratoga Streets from 1885 to 1940.

As an example that the idea of these associations flourished, the Minneapolis group held their 449th meeting in 1965. Also, they have contributed greatly to the social and professional life of many who have given much to the development of pharmacy throughout the country.

For many years, Veterans' luncheons were held regularly at the conventions of the American Pharmaceutical Association and the National Association of Retail Druggists. Every "veteran druggist" in attendance at these affairs was urged to attend the luncheon which measured up to true "frater" standards. As early as 1928, a "veterans" meeting was held at the APhA annual convention in Portland, Maine.

William Bodeman was one of the pioneer builders of the National Association of Retail Druggists in 1898. During the annual meeting of the APhA held at Indianapolis in 1906, the National Pharmaceutical Syllabus Committee (a) was organized and Bodeman representing the National Association of Boards of Pharmacy was added to the original committee. In 1928, at a joint meeting of the Baltimore and Washington Veteran Druggists' Associations, a letter of greeting and good will, signed by each one present, was sent to Frater Wilhelm Bodemann of Chicago, who was described as the "originator" of the Veteran Associations and who has taken a deep interest in the various organizations which have been effected.

The second meeting of the Baltimore Veteran Druggists' Association (B.V.D.A.) was held at the Rennert Hotel on October 6, 1926. The report of the Committee on Details of Organization was read, the items contained therein discussed, and the following additions or changes adopted: (1) the membership shall consist of active, associate and honorary members; (2) active members shall be or shall have been engaged in dispensing pharmacy; (3) associate members shall be engaged in teaching, the wholesale drug business, manufacturing pharmacy or in some activity closely related to pharmacy; (4) persons of distinction, engaged in or interested in pharmacy, may be elected as honorary members; (5) the number of active members shall be limited to twenty-five and of associate members to fifteen; (6) meetings shall be held on the third Wednesday in each month; (7) the birthday anniversary of each member shall be celebrated at the first meeting following the date on which it falls; (8) the floral emblem of the Association shall be a white carnation (the writer well remembers Dean DuMez wearing this flower at the school after a meeting); (9) all funerals of members shall be attended by the entire Association and following a short speech by the president, the members shall drop a flower into the grave while saying in unison "Our last loving tribute to our departed Brother ______________ . We knew him, we loved him, we shall miss him. Farewell, Frater, rest in peace." Also, at this meeting the following were elected to membership: Charles Morgan, member of the well-known firm of Morgan and Millard; Howell W. Allen, proprietor of a drugstore at 25th and Oak Streets and member of the Publication Committee Maryland Pharmaceutical Association; Edward R. Downs, proprietor of a drugstore, North and Linden Avenues; J. Emory Bond, 703 West Lanvale Street; and J. W. Dorman, proprietor of a drugstore, Collington Avenue and Jefferson Street.

In 1943, Secretary DuMez stated that, "The primary objective of the organization is to promote good fellowship among pharmacists who have been engaged in the profession for 25 years or longer."

For many years, the local organization looked forward with pleasure to the joint meetings held with the District of Columbia Veteran Druggist Association. The first meeting was in 1928 at Carvel Hall in Annapolis. The occasion was much enjoyed by the veterans from the two cities.

Meetings were also held with the Washington group at the Olney Inn, Montgomery County (1913, 1933–37, 1939, 1950, 1952, 1954); Log Inn on the Chesapeake Bay near Annapolis on the Sandy Point highway (1949); Floyd's Restaurant (b) northeast corner of St. John's Lane and Route 40 West (1951, 1953, 1955, 1957); and at the Hot Shoppe, Langley Park near Washington (1956).

At these get-togethers, each group provided entertainment and dinner on a Dutch Treat basis. Also, at some of these joint meetings, the ladies were invited. In 1964, it was reported to the Baltimore Veterans that the District of Columbia Veteran Druggist Association (D.C. V.D.A.) had been inactive for several years.

For many years, the Association made annual Christmas donations to many groups in the Baltimore area for use of those in need of assistance. The following are examples of some of the recipients: Santa Claus Anonymous, Augsburg Lutheran Home For Children, The Mission Helpers—conducted a school for deaf children, Sinai Hospital Childrens' Ward, Convent of the Good Shepherd, and the Pine Street Police Station Poor Fund.

A special celebration was held at the 150th meeting in September 1945 with 30 members present. The June 1949 meeting was held in the new building of the Noxzema Chemical Company on Falls Cliff Road in the Hampden area of Baltimore. The dedicatory speaker was Dr. H. C. Byrd, president of the University of Maryland, and also a member of the B.V.D.'s. The dedicatory ceremony was followed by a tour of the new building and an enjoyable luncheon. Approximately 1500 persons were present at the dedication of the building.

As previously mentioned, in 1926 the active membership was limited to 25 and that of associate members to 15. However, in 1950 the rules and regulations of the Association were revised to active and honorary membership only, with active members limited to 75. All associate members at that time were elected to active membership, unanimously.

(a) Outlined courses of instruction for the degrees of Graduate in Pharmacy (Ph.G.) and Pharmaceutical Chemist (Ph.C.).

(b) Owner was Melvin L. Floyd, School of Pharmacy graduate, class of 1938.

The members of the Association have always constituted a remarkable roster of prominent Baltimore pharmacists and those interested in pharmacy. The high calibre of the membership is shown by the background and interests of the charter members.

B.V.D.A. members have been very active in national and local pharmaceutical drug organizations; the alumni groups of the old Maryland College of Pharmacy, the University of Maryland, and the School of Pharmacy; as well as politics (one was elected to the Baltimore City Council and later to the State House of Delegates, another was Liquor Commissioner of Baltimore, a third member was not only a City Councilman, but also a Magistrate and member of the Zoning Board).

Noteworthy of recording is that members of the local veterans group were presidents of the following organizations: *American Pharmaceutical Association*—Eberle (1910), Dohme (1916), Dunning (1929), Swain (1933), and DuMez (1939); *Maryland Pharmaceutical Association*—Dohme (1899), W. E. Brown (1903), Fouch (1908), Thomas (1909), Morgan (1910), Hancock (1911), Frames (1913), Bunting (1915), Hodson (1917), Millard (1919), Williamson (1921), Meyer (1923), Harris (1925), Dunning (1926), H. W. Allen (1928), Kantner (1932), Ludwig (1934), Strasburger (1936), Swain (1937), Hewing (1939), Black (1943), Harrison (1945), Austin (1947), Diener (1949), Waples (1951), Muelhause (1953), Davidov (1955), Frank Block (1958), Weiner (1964); *Travelers' Auxiliary Maryland Pharmaceutical Association*—Neal (1919), Hendler (1920–21), Armstrong (1927), Love (1932), Keppler (1933), L. B. Wright (1935), Leatherman (1936), Weyprecht (1944), Vogel (1946), Crozier (1948), Dawson (1949), Hugg (1954); *Alumni Association School of Pharmacy*—Lowry (1926), Harrison (1930), Rettaliata (1932), Black (1933), Hewing (1934), Davidov (1935), Wannenwetsch (1936), Strevig (1937), Austin (1939), Muelhause (1941), R. H. Wagner (1945), Andrews (1946), Joseph Cohen (1948), Frank Block (1950), Balassone (1951), Raichlen (1952), Warfield (1957), I. I. Cohen (1960), Friedman (1963), Libowitz (1966), Ichniowski (1967), Gruz (1968); and the following served as *Honorary Presidents:* Morgan (1931), Wich (1932), Fouch (1935), Harris (1940), Sonnenburg (1941), Hodson (1943), Stevens (1945), Dunning (1948), Sencindiver (1949), Bunting (1950), Cole (1953), Black (1954), Wannenwetsch (1955), Austin (1957), Lowry (1958), Helm (1959), Strasburger (1963), Davidov (1965), Frank Block (1967), Spigelmire (1969), Wooten (1970), Cooper (1971), Slama (1973); *Baltimore Retail Druggists' Association**—Thomas (1909–10), Williamson (1912–28), Harris (1929–32), Wannenwetsch (1935), Kronthal (1936), Waples (1940), Austin (1941), Harrison (1942), Muchlhause (1943), Settler (1946), Cooper (1948), Davidov (1949), Frank Block (1953).

There has always been a wealth of experience contained in the membership of the Baltimore Veteran Druggists' Association and pharmacy is indeed fortunate in having such an organization where the past, present and future is blended together. The group cooperated in the centennial celebration of the Pharmacy School in 1941. The following served as Chairmen of the different committees: Muehlhause, General Chairman; Andrews, Reception and Dance; Cole, Program; Davidov, Publicity; DuMez, Session on Education; Dunning, Finance; Harrison, Banquet; Helm, Registration; Strevig, Reservations.

Also, the following veterans have been recipients of the *Honored Alumnus Award* given by the Alumni Association School of Pharmacy: Dunning (1949), Swain (1950), Bunting (1951), Cole (1953), Black (1955), Wannenwetsch (1956), Kantner (1959), Joseph Cohen (1961), Foss (1962), Slama (1963), Balassone (1965), Warfield (1968), Frank Block (1970).

In 1949, Frank L. Black was elected the first President of the newly formed University of Maryland Alumni Club of Baltimore and in 1959 Frank Block served as President of this same group.

The following charter members of this association graduated from the old Maryland College of Pharmacy located on Aisquith Street, two doors north of Fayette Street: H. W. Allen (1895), Bond (1886), Bunting (1899), Dorman (1894), Dunning (1897), Fouch (1886), Frames (1882), Harris (1890), Kelly (1902), Meyer (1892), Millard (1891), Morgan (1891), Neal (1899), Thomas (1872).

A number of the founding fathers were also officers, at one time, in the Alumni Association of the Old Maryland College of Pharmacy. Charles C. Neal was Recording Secretary in 1899, J. Emory Bond, President in 1903, John B. Thomas, First Vice-President in 1903, and E. F. Kelly, Secretary in 1904.

In addition to practicing community pharmacists, the membership has included a President of the University of Maryland (H. C. Byrd); a Chairman of the Board, Emerson Drug Company (Joseph F. Hindes); the General Manager of the Pharmaceutical Laboratories, Sharp & Dohme (Charles C. Neal, who also donated flowers for Alumni banquets from 1926 until his death in 1938); the President of the Baltimore Drug Exchange in 1957 (William C. McKenna); a pharmacist-in-chief to the Johns Hopkins Hospital (R. S. Fuqua who had many years of experience in hospital practice and was interested in all matters pertaining to professional and ethical pharmacy); and John C. Bauer, recipient of the first Doctor of Philosophy degree from the School of Pharmacy, University of Maryland and who in 1935 presented a paper entitled "The Possibility of Clinical Service As a Phase Of Pharmaceutical Practice."

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* The name was changed in 1958 to the Baltimore Metropolitan Pharmaceutical Association.

1986 OFFICERS

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Any members who wish to join the BVD can do so by contacting President Frank Block—BVD—meeting 3rd Wed. of every month—Duffy—West View Mall

Versatility—The Core of New Computer Program From Lilly

A versatile new computer program designed to help pharmacists operate a more profitable pharmacy has been introduced by Eli Lilly and Company and Dista Products Company, Indianapolis, Indiana. Available to all retail pharmacists, it was recently previewed at the NARD convention in Louisville, Kentucky, where participants were treated to a "hands on" demonstration of the first unit, "Managing cash flow for increased profitability."

This new program will prove invaluable to the retail pharmacy. In addition to an explanation of the basic concepts of cash flow, the program covers topics, such as "sources and uses of cash" and "cash shrinkage." Also included are helpful hints for managing receivables, billing, and inventory—all arranged in a "user friendly" format. And the text on the screen is liberally illustrated with easy-to-understand flow charts and colorful bar graphs.

The versatile format of the program allows accessing pharmacists to evaluate their pharmacy's profitability status by performing multiple "what if" analyses. This "what if" structure enables pharmacists to enter their own pharmacy's financial data and then to manipulate the numbers in various ways in order to arrive at the most beneficial cash flow scheme.

In addition to its function as a learning and educational tool, the new computer program can be used as a data storage bank. It can hold a substantial amount of data, with all information kept strictly confidential and inaccessible to anyone other than the designated operator. Thus, it is a truly cost-effective means for both learning and financial data storage.

Another special feature available through the new computer program is the free Lilly Analysis Service. Because a pharmacy's financial data reflect its strengths and weaknesses, it is extremely important that this information be properly interpreted and utilized. The purpose of the complimentary service is to locate areas that may present potential problems, offer suggestions for improvement, as well as to identify operations which are functioning well. By participating in the Lilly Analysis Service, the pharmacist can obtain the benefits of a "private" financial consulting firm without having to pay the high cost.

Any pharmacist wishing to participate merely inputs financial data on the program diskette provided and then sends the diskette to Lilly. After these figures are received, they are audited and a computer printout is generated. This printout is then analyzed by staff experts, comments are made, and the report is sent directly to the designated address. All data are kept *strictly confidential*. Again, there is no charge for this service.

With data submitted through the new computer program, Lilly publishes the *Lilly Digest*. The *Lilly Digest* is a compilation of operating statistics from independent retail pharmacies located throughout the United States. It is designated as an aid which pharmacy managers and owners may use in order to evaluate the operations of their own stores. Eli Lilly and Company publishes the *Lilly Digest* annually as a service to community pharmacy in the interest of sound business management.

The final element of this innovative disk program is the opportunity for continuing education credits. On completion of a test at the end of the unit, the pharmacist is awarded a certificate for 2 credit hours (ACPE), which are sent directly from Lilly.

Analysis, learning, and continuing education credits are only the primary components of this inaugural electronic interaction program for the pharmacist. Eli Lilly and Company and Dista Products Company are pleased to offer this dynamic new computer program, which is designed to help the independent retail pharmacist operate a more profitable and sound business.

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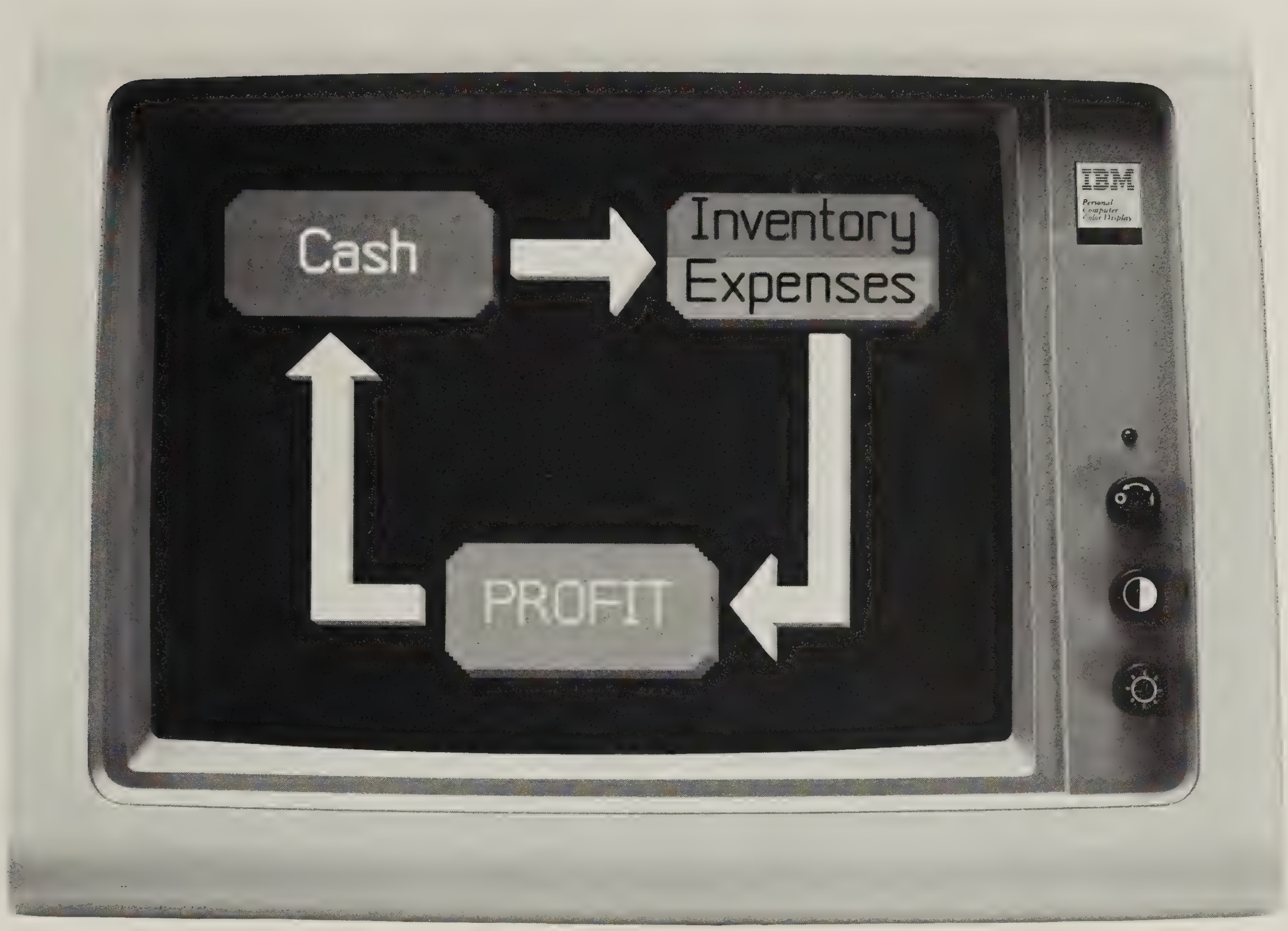

And they could lead you to greater profits. With the help of the new Lilly Computerized Pharmacy Management Series, you can learn key cash management techniques that may be employed for operating a more profitable pharmacy. But you also earn as you learn. On satisfactory completion of a test at the end of each unit, you receive 2 hours (0.2 CEU) of continuing education credits.

With the aid of this "hands-on" program, you'll be moving in the right direction...toward increased profits.

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PHARMACY ACHIEVEMENT SCHOLARSHIP
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School of Pharmacy

The University of Maryland School of Pharmacy's Annual Pharmacy Achievement Scholarship represents an exciting challenge to you as a practitioner concerned with the future of our profession. By sponsoring a qualified high school or college student (Maryland Resident) for this tuition-free one-year scholarship, you will:

1) stimulate general community interest in the profession;
2) encourage one outstanding young person of your acquaintance to choose pharmacy as a career;
3) demonstrate to your colleagues an awareness of the need for more and better pharmacy students.

The guidelines are simple. The student that you sponsor must have a satisfactory record of achievement in high school or college, an interest in pharmacy as a career, a cumulative grade point average of 2.75 or equivalent, and PSAT/SAT scores ready for submission. He or she then completes the Student Section of the form enclosed, while you complete the Pharmacist's Section. *You* then *mail both forms*—to be received no later than midnight December 15th—to:

The Pharmacy Achievement Scholarship Committee
University of Maryland-School of Pharmacy
20 North Pine Street
Baltimore, Maryland 21201

That's all there is to it.

The recipient will be selected by representatives of the School of Pharmacy, the Maryland Pharmaceutical Association, the Alumni Association, the Maryland Pharmaceutical Society and the Maryland Society of Hospital Pharmacists. The award (one year's tuition) will be announced at a formal ceremony for all nominees and sponsors at the School of Pharmacy during the Spring term. The recipient will be required to meet established admission requirements for the School of Pharmacy at the time of entry.

For additional forms or further information, call Dr. Grady Dale, Assistant Dean for Student Affairs, 528-6586.

UNIVERSITY OF MARYLAND
PHARMACY ACHIEVEMENT SCHOLARSHIP

APPLICATION
(Please type or print)

PHARMACIST'S SECTION

I nominate ______________________ for the School of Pharmacy Annual Pharmacy Achievement Scholarship.

Pharmacist's Name: ______________________

Address: ______________________

Name of Pharmacy: ______________________

College of Pharmacy: ______________ Degree ________ Year ______

Telephone # ______________________

Indicate below why you feel this student is deserving of this scholarship. Include how you came to know the student and his/her qualities and attributes. Also include your knowledge of his/her extra-curricular activities and how the student has demonstrated an interest in pharmacy as a career.

Please make sure the student you have nominated has completed all the information on this application before sending to the Scholarship Committee.

Sponsoring Pharmacist's Signature

Date

Send completed form to:
Pharmacy Achievement Scholarship Committee
University of Maryland-School of Pharmacy
Baltimore, Maryland 21201

STUDENT SECTION Date of Application

Name: Telephone #

Address:

Permanent Address (if different from above)

List your most recent place(s) of employment (if any):

Employer *Dates of Employment* *Brief Description of Duties*

1.

2.

*Indicate any extracurricular (social or service) activities.***

*Briefly, how did you become interested in pharmacy as a career?***

*Describe how you came to know the pharmacist nominating you for this scholarship.***

Include transcript of high school grades (college transcript if beyond first year of college). PSAT, SAT and/or ACT scores must be submitted if not included on transcript. NOTE: The awarding of the scholarship does not constitute admission to the School of Pharmacy. The recipient must be a bona full-time student at the University of Maryland School of Pharmacy in order for the scholarship to be activated.

Student's Signature

**Note: DO NOT WRITE OUTSIDE of the box or attach additional information. To do so may void the application. THIS APPLICATION MUST BE RECEIVED NO LATER THAN DECEMBER 15th.

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During this past summer, pharmacists from across the United States and Puerto Rico were invited to enter a drawing to support pharmacy education.

For every winning entry — 156 in all — Burroughs Wellcome Co. pledged to donate a $500.00 scholarship to a pharmacy school and a matching $500 grant to one of six national pharmacy associations of the winner's choice.

To everyone who entered the drawing, thank you very much. And to the following winners, our most sincere congratulations:

Lori Ann Thomas
Rockville

Richard M. Taffet
Rockville

Daniel S. Shaner
Ellicott City

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CALCIUM USE IN AN AMBULATORY, COMMUNITY-LIVING POPULATION

by Joy V. Williams, Madeline Feinberg, Peter P. Lamy

INTRODUCTION

The use of calcium for the prevention of osteoporosis and related fractures has been heavily promoted in the recent past, even though the data regarding its effectiveness are still ambiguous. There are no data to show that it can restore bone structure, once loss has been initiated. Even though, when the FDA approved the use of oral estrogens (except the oral contraceptives) for the treatment of postmenopausal osteoporosis, it noted that these products ''should be used with other important measures, such as diet, calcium, and physiotherapy''. The National Institute on Aging, the Office of Technology Assessment, and other organizations have targeted osteoporosis for heightened attention. Dr. Brody has noted that if one could delay the onset of osteoporosis, one could extend the active life expectancy.

Consequently, attention has been focused on calcium and osteoporosis not only in the scientific/professional literature, but even more so in the lay press and the media. A host of new products has reached the market, each advertised heavily. Therefore, it was of interest to see how a sample population responded.

In the more recent past, there has also been some discussion regarding the possibly beneficial role of calcium in hypertension (still a hypothesis) and its possibly preventive role in colorectal cancer. It has been proposed that the absence of calcium could be responsible for cell proliferation and, thus, cancer. There have also been expressions of caution, noting that undirected and unsupervised use and overuse of calcium could have deleterious effects.

THE SURVEY

It was the goal of this survey to question a sufficient number of clients of two community pharmacies until 100 had been identified who were taking calcium. They would then be asked to participate in the survey (all agreed), the survey would be explained, and questions would be asked via a questionnaire by one surveyor. Two community pharmacies agreed. The information to be obtained was demographic (age, sex, race), when calcium use was started, whether it was prescribed by a physician, why the user started taking it, who recommended it or how did it come to the user's attention, and the brand of calcium taken. As a correlary, users were also asked whether or not they were taking any other vitamin/mineral supplements.

RESULTS

Approximately 315 clients entering the two Baltimore community pharmacies consecutively at different times during the winter 1986 were questioned, until 100 users were identified. Thus, somewhat less than one-third of the sample population was using calcium.

The Calcium User: Females, as expected, predominated, even though calcium use has also been recommended for older males. Females constituted 94% of the user group, and males 6%. Of the users, 59% were white, and 41% were black. Incidentally, 24% of calcium users also were taking some type of vitamin, 5% were taking iron, and one person was taking zinc.

The age of the users ranged from 20 years to 85 years (Table I).

From the data in Table I, it is apparent that the ''middle-aged'' group, i.e. those between 55 and 69 are the heaviest users (32%), followed closely by those in their 40s and early 50s (29%). Surprisingly, those 70 years and over, at least in this sample, use calcium more often (22%) than the youngest age group surveyed (17%). Apparently, data that have shown that a negative calcium balance often exists in females in this young age group has not yet made the impact it probably should, since calcium is most likely better suited in prevention than treatment. Obviously more attention

---

This study was, in part, supported by a grant from the Merck Foundation and The Center for the Study of Pharmacy and Therapeutics for the Elderly.

Joy V. Williams, at the time of the study, was a senior pharmacy student. Ms. Feinberg is Assistant Clinical Professor and Director, Elder Health Program, and Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, School of Pharmacy and Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD 21201

TABLE I
The Age of Calcium Users

Age Range	Percent
20–24	2
25–29	4
30–34	7
35–39	4
40–44	9
45–49	9
50–54	11
55–59	10
60–64	10
65–69	12
70–74	9
75–79	7
80–84	5
85 and over	1

must be focused on this age group.

Duration of Calcium Use: Use ranges from 1 day to 15 years. According to survey data, 37% has been taking calcium for two or more years at the time of the survey, 14% had been taking calcium for 5 years and longer and 5% has been taking it for 10 years and longer. Of the participants, 52% were taking calcium one year or less, and 48% were taking it longer than that. Apparently, the public health message on calcium and osteoporosis is needed, at least to some degree.

Why Are People Taking Calcium? It was interesting to review the reasons given for calcium use. There was not one respondent who mentioned hypertension or colorectal cancer. The most frequently given reasons are listed in Table II:

TABLE II
Reasons for Calcium Use

Reason	Percent
Fear of osteoporosis	36
Prescribed by physician	13
Reduced dairy intake	10
Falls or fears of falls	6
Family member has been taking	5
Getting older	5

Fear of osteoporosis included many things. Not infrequently, people stated that they "don't want to look like the TV lady", obviously referring to a TV ad which was shown at the time of the survey and which depicted an elderly lady severely bent over. Fear of osteoporosis also included, falls, and, in some instances, calcium was taken to help with osteoporosis and arthritis.

The terms *prevent* and *protect* occurred numerous times, showing that clients are, indeed, interested in preventive health measures.

It was also interesting to note the relatively high number (13) of patients for whom a physician had prescribed calcium. In three incidences, the prescription followed X-rays, and two patients were given calcium "because of arthritis or osteoporosis". The number of times that "reduced dairy intake" was listed indicates that people are becoming more conscious of the value of nutrition.

It was bemusing to study the term "getting older", which was given, among others, by a 25 year old and an 82 year old.

That there is still a great deal of general confusion about the projected beneficial effect of calcium is attested to by many of the answers. People were looking for "better sex", had hair problems, teeth problems, general health problems, bone marrow problems, suffered from tiredness (several times) and from gas. Apparently, taking calcium "is the healthy thing to do" for whatever reason.

Where Do People Learn About Calcium? The most often mentioned sources of information are given in Table III:

TABLE III
Frequent Sources of Information on Calcium

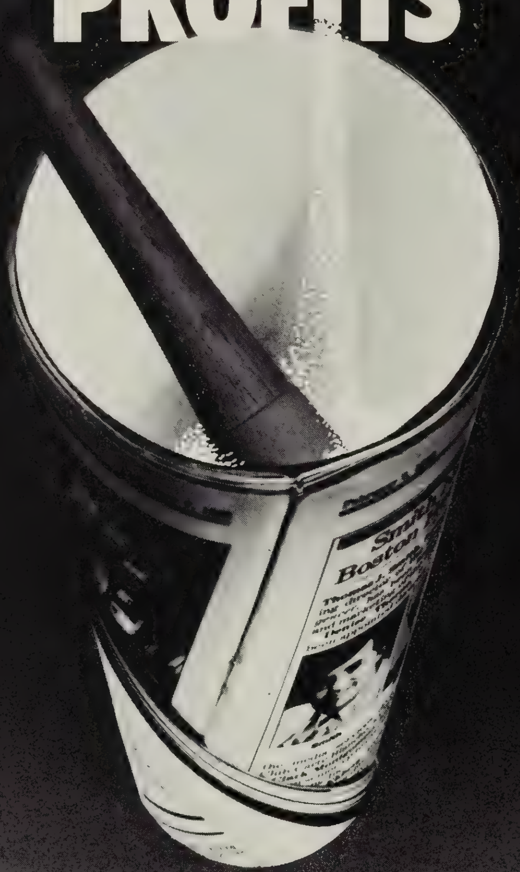
Source	Percent
Television	28
Pharmacist	24
Family/friend	23
Newspaper/magazine	17

The power and influence of the media is apparent from the data in Table III. It was most interesting that the "Donahue" show was mentioned by name several times. The influence of family and friends is not unexpected, but the relatively poor showing of pharmacists is cause for concern. As noted previously, calcium use has been heavily promoted. Moreover, pharmacists should recognize calcium use and its role on osteoporosis as a public health issue and an issue that needs their support.

Even more importantly, as more and more Rx drugs are switched to OTC status, pharmacists will need to address their clients more forcefully, if they wish to retain that market. Already, less than 50% of all OTC items are being sold in Pharmacies. If one believes the predictions that, by the end of the century, about 50% of all chronic care drugs will be available OTC, then pharmacists must begin to develop better strategies to inform their clients about OTC drugs and to become the center of OTC drug sales in their community.

What Calcium Is Being Used? Tums, Caltrate and Oscal were probably most often used, but none emerged as a market leader, and none achieved use by even 10% of the respondents. It was curious to see that, several times, when physicians prescribed or pharmacists recommended calcium use, Tums were used. Among others that were used were Rolaids, sea shells, bone meal, chewing gum and a whole host of other products. Thus, while there appears to be at least some success in convincing people that calcium may be needed (52% of respondents had started to take calcium within a year of the survey), no company manufacturing calcium products has achieved name recognition among the sample population. As a matter of fact, many respondents could not recall the brand of calcium used and, surprisingly, many stated that they used "the cheapest available, since calcium is calcium".

PERIODICALS COMPOUND YOUR PROFITS



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Our 1986 Pharmacy Consultant Panel gave us a good, hard look from eleven very critical vantage points: Their personal experience in pharmacy.

Some things they told us made us feel proud. Some things made us see the need for change. Most importantly, they pointed us in some exciting new directions. The result? A better understanding of the way things are, and should be, for both you and your customers.

They might have spared our feelings by telling us what they thought we'd like to hear.

But they didn't. And we're glad.

Meet our 1986 Pharmacy Consultant Panel.

Standing Left to Right:

Charles Lippert, Pharmacist
President
Evans Pharmacies Inc.
Zeeland, Michigan

Reed Rosling, Pharmacist
Vice President
Hospital Sales
Bergen Brunswig Drug Co.
Orange, California

John Kogut, Pharmacist
Senior Vice President
Fay's Drug Company
Liverpool, New York

Marily Rhudy, Pharmacist
President
Continental Pharmacy
Topeka, Kansas

M. Patricia Lee, Pharmacist
Director of Pharmacy
University of California
San Diego Medical Center
San Diego, California

Seated Left to Right:

Jack R. Cole, Pharmacist
Dean, College of Pharmacy
University of Arizona
Tucson, Arizona

Darwyn Williams, Pharmacist
President
Williams Drug Inc.
Webster City, Iowa

William Thien, Pharmacist
Vice President
Health Services and
Pharmacy Operations
Walgreen Drug Stores
Deerfield, Illinois

John Piecoro, Jr., Pharmacist
Associate Director
Clinical Services
Chandler Medical Center
Lexington, Kentucky

Bernard Mehl, Pharmacist
Director of Pharmacy
Mount Sinai Hospital
New York, New York

Not pictured: Larry Braden, Pharmacist, Executive Vice President, Georgia Pharmaceutical Association, Atlanta, Georgia

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Question #5

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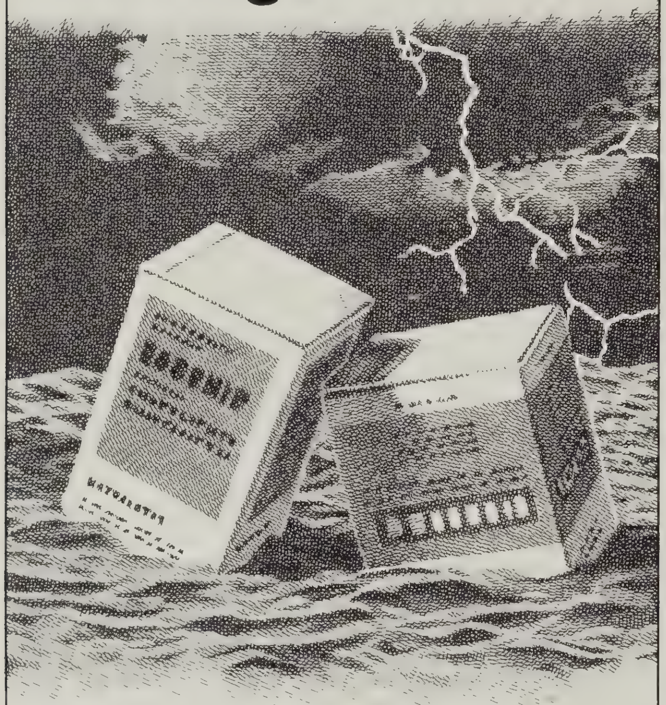

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'Tween Scripts

By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.

Honoring Pharmacy's "Extra Effort" People

Again this fall, current year recipients of the A. H. Robins "Bowl of Hygeia" Award, selected by their peers through their professional pharmacy associations in the 50 states, the District of Columbia, Puerto Rico, and the 10 Canadian provinces were invited to be guests of our company for a special salute in our Richmond headquarters.

The four-day event included receptions and dinners, tours of our manufacturing and research facilities and a sightseeing trip to Williamsburg, the restored colonial capital of Virginia.

It was a desire to encourage pharmacists to take more active roles in community affairs that prompted E. Claiborne Robins, chairman of the board of A. H. Robins Company and a pharmacist himself, to establish the "Bowl of Hygeia" Award in 1958. The award provides special recognition to the men and women of pharmacy for their many and varied community services.

Some have served in their state legislatures and on city councils. Others have filled important positions on planning and zoning commissions and hospital, school and other boards. They have provided leadership for fund drives and countless special projects, and have participated in the work of youth organizations, civic clubs, churches and fraternal organizations. Perhaps a quarter of the over 1,500 recipients thus far have headed their state or provincial pharmaceutical associations at one time or another.

The award is a handsome plaque featuring the Bowl of Hygeia cast in bronze. So that they may be recognized wherever they go, award winners are also presented lapel pins which are scale replicas of the plaque, and at any gathering of pharmacists, those wearing the pin form a proud "alumni" of previous recipients.

A. H. Robins is pleased to be able to assist state and provincial associations in recognizing these "extra effort pharmacists."

Jake Miller

A·H·ROBINS

A. H. Robins Company
Richmond, Virginia 23220

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METRO CRIME STOPPERS
...The Program That Works.

METRO CRIME STOPPERS helps control crime in Baltimore City and Anne Arundel, Baltimore and Howard Counties, making life safer and more pleasant for over two million residents and visitors.

METRO CRIME STOPPERS has received and processed over 1,000 anonymous telephone calls to the Hotline, 276-8888. Nearly one-third of those crimes — murder, rape, robbery, assault, burglary, theft, and arson — have been solved. Over 200 arrests have been made and an 87.5 percent conviction rate has resulted from those cases which have been prosecuted.

Here's how it works: Knowing there is the possibility of a cash reward, and knowing they may remain anonymous, people call the METRO CRIME STOPPERS Hotline, 276-8888, with helpful information about a crime. A special code number is assigned to the caller, who can then receive status reports on the case by using that special code number.

Information on the crime is passed along to the detective working on the case. If that particular case has the detective stumped, there are no viable leads, and the tip is really valuable, the Police Council might suggest a $1,000 reward. Or if the detective is just hours away from solving the crime, but the information supplied is valid, the Police Council might recommend a $100 reward. The amount of the reward is approved by the Board of Directors and paid upon arrest and indictment of the suspect.

The Board of Directors of METRO CRIME STOPPERS (30 business and lay people from our communities) raises the funds needed to pay the rewards. Board members publicize the Hotline number and work with the Police Council.

The Police Council, composed of representatives from Baltimore City and Anne Arundel, Baltimore and Howard Counties, meets regularly to select the cases for television reenactment. They recommend the reward amounts, provide personnel to answer the Hotline, and work to build community awareness of the program.

WJZ-TV (Channel 13) videotapes a reenactment of a "crime of the week" for broadcast on the Monday Evening News and the Tuesday Morning and Noon News. The electronic and print media include the METRO CRIME STOPPERS Hotline number and reward offer when covering the crime beat.

METRO CRIME STOPPERS, a private, non-profit group, is part of a network of METRO CRIME STOPPERS organizations in the United States and Canada.

METRO CRIME STOPPERS HOTLINE
276-8888

The Baltimore Metropolitan Pharmaceutical Association was a charter member of Metro Crime Alert.

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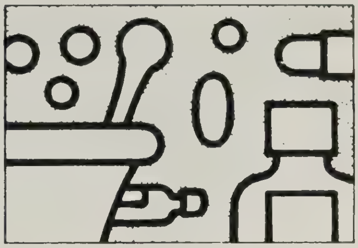
NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION

Things You Should Know FOR YOUR GOOD HEALTH



Treatment of Head Lice

One problem that seems to turn up every fall, shortly after school starts, is head lice. It has become almost routine to have several schools report infestations of head lice. It is not always the same schools. Head lice can strike anywhere. Reports from the health departments and school systems indicate infestation has markedly increased in the United States in recent years and is now affecting both children and adults.

Lice are wingless parasites with well-developed legs. Each leg has a claw that helps the louse cling firmly to the skin while sucking blood. Three types of lice attack humans: head lice, body lice and pubic lice.

Head lice usually infest the head; they can, however, be found on other hairy parts of the body. The female lays 50-150 eggs, which become attached to the hair and hatch in five to ten days. Body lice live, hide, and deposit their eggs in clothing, specifically in seams and folds of underclothing, and generally infest crowded environments. It is a popular belief that head lice will only thrive in an unclean environment. But this is a false assumption. Head lice in no way imply poor housekeeping or a lack of personal cleanliness.

Head lice come from direct contact with another person or indirect contact through the use of lice-infested clothing, bedding, hairbrushes or combs. Do not blame your child if he gets head lice. It has nothing to do with how often he shampoos his hair or takes a bath. Children can pass head lice from one to the other when they play together, when they exchange hats, when they put on someone else's jacket or sweater, or when they share combs and hairbrushes.

Head lice eggs, called nits, are small, oval and whitish in color. They attach to the hair shafts near the scalp, especially at the nape of the neck and in back of and above the ears. The lice are often not seen because they are usually present in very small numbers. Bites by lice and the accompanying scratch marks can usually be seen. The nits resemble dandruff, but dandruff is flat and is easily removed from the hair. Nits are not. They are attached to the hair shaft with a glue-like substance and cannot be removed easily by pulling on them.

Also, contrary to popular belief, intense itching is not always present when a person is infested with head lice. It usually is, but a person might have head lice and not feel any discomfort. There are special shampoos that will get rid of the lice. Ask your pharmacist to recommend a product if you find head lice on your child.

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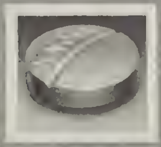

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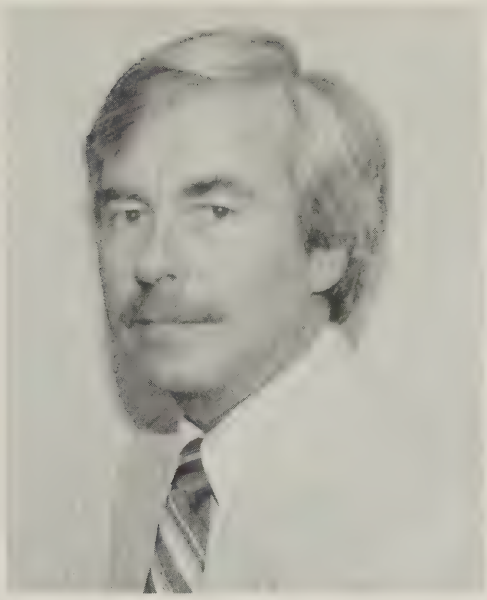
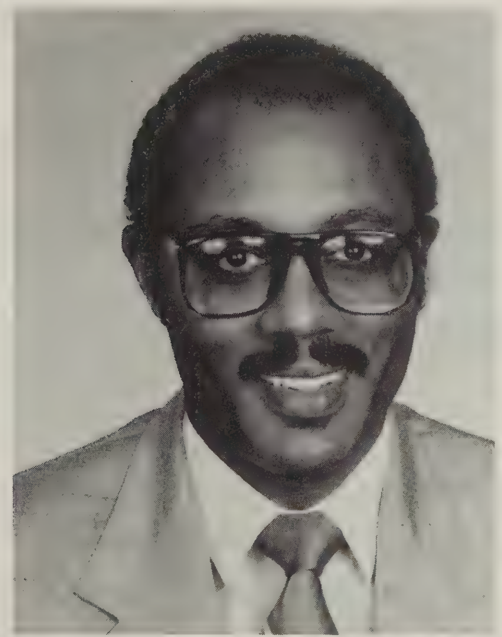
Cynthia Kulinski has been newly assigned to the Baltimore area to represent Abbott Laboratories. She is a graduate from Towson State University.



Thomas Arthur, former executive director of the Colorado Pharmaceutical Association, has been named director of state relations and regional director of membership development for the National Association of Retail Druggists.



Gregory E. Merriweather is a new Syntex representative assigned to the Baltimore area. He is a graduate of George Washington University.

Estelle Cohen, former consumer member to the Maryland Board of Pharmacy, now serves as a consumer representative to the United States Pharmacopeial Convention.

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In order to promote that goal, the Healthy Majority needs committed volunteers. Undoubtedly, there are many pharmacists who would like to work with the Healthy Majority. If you are one of these people, here are some of the things you can do:

- Display Healthy Majority "No Smoking" table tents in your store
- Recruit additional members
- Be a part of a speakers bureau
- Contact your state and county legislators about the issues
- Attend a monthly Healthy Majority meeting in Baltimore as the official MPA representative
- Be a part of a public relations committee

If you are interested, please contact Robin Shaivitz at 685-7074 and let her know what you would like to do. Thanks, in advance for your support.

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PRECEPTOR ORIENTATION MEETING

In January 1987 the Professional Experience Program (PEP) will welcome additional preceptors into the program. An orientation program for potential new preceptors will be held at the School of Pharmacy Thursday, November 20, 1986 at 7:00 P.M. To maintain a balance of opportunities the specific needs for preceptors in specific practice types and geographic areas vary from year to year. The evolution of pharmacy practice has increased the need to provide training in specialized practice areas such as HMO's, Nursing Homes, Home Care, etc. The basic quality required of a preceptor is a willingness to share with students that which one has learned through experience.

Pharmacists interested in teaching and becoming part of the preceptor faculty can contact the program director, Marvin L. Oed at Pharmacy Hall, 20 N. Pine Street, Baltimore, MD 21201 or telephone 528-7118.

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Nov. 23 (Sun)—MPhA Dinner Theatre. Burn Brae
Jan. 14–25—MPhA Trip to Hawaii
Jan. 16–18—MPhA/Alumni Ski Weekend at Hunter Mountain
Feb. 8—MPhA New Year meeting
March 8—BMPA Annual Dinner Dance
March 28–April 1—APhA annual meeting
April 28–May 2—NARD midyear meeting
May 17—CECC Seminar on Arthritis

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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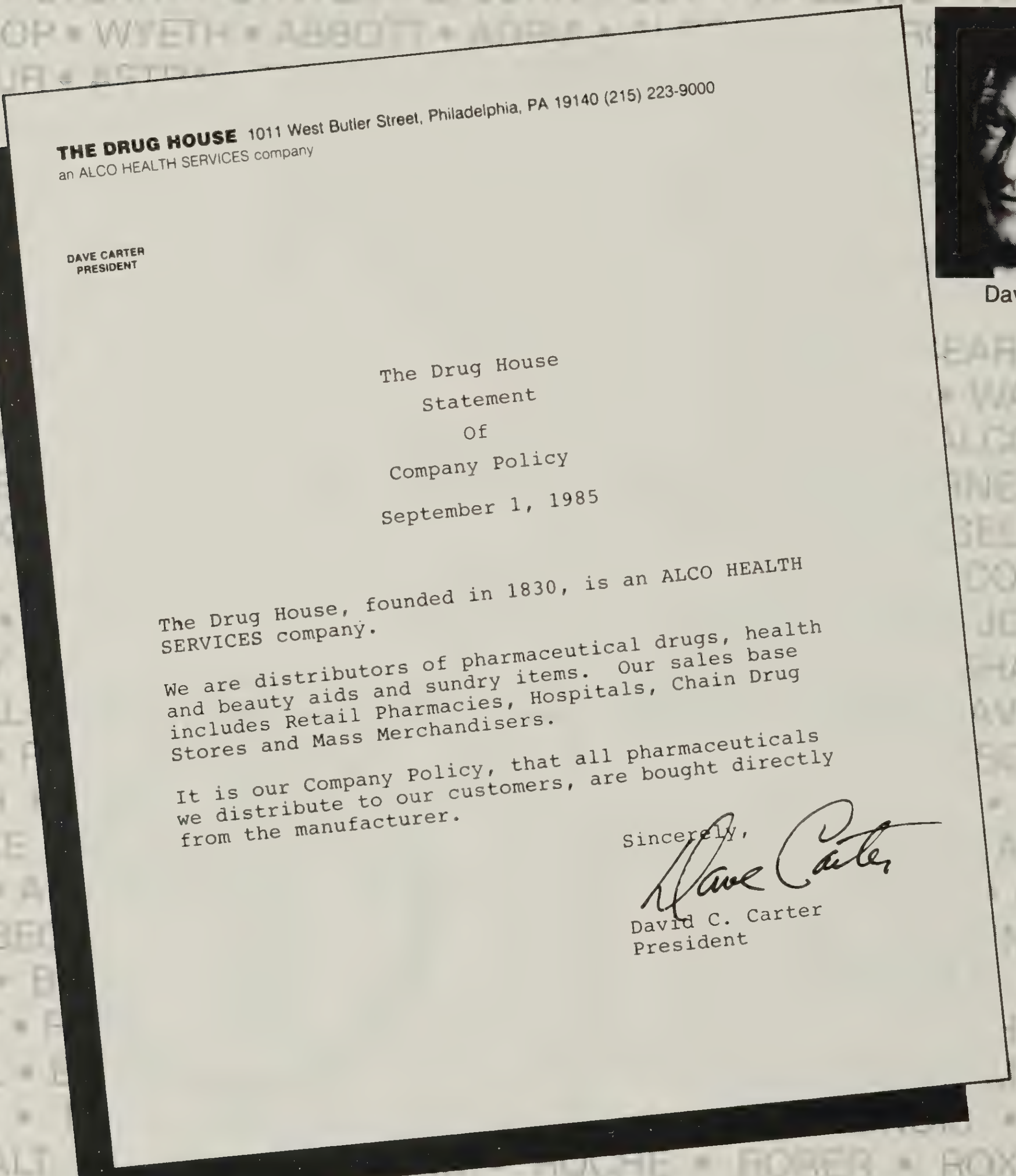

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THE
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OTC Antitussives and Expectorants

— Thomas A. Gossel
— J. Richard Wuest

1986 Salary and Benefits Survey

— Richard Reitz
— Dudley Demarest

Case Management of the Frail Elderly

— Lucinda L. Maine

NSAID-Induced G.I. Effects: Risk to the Elderly

— Peter P. Lamy

Compounder's Corner

— Loyd V. Allen, Jr.
— M. Lou Stiles

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DECEMBER, 1986 NO. 12

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Guest President's Message

There is no question that the role of the pharmacist is expanding in the health care field as the twenty-first century approaches. Right now we are fighting for prescribing rights and a place in home health care. We do consulting in nursing homes and see patients in clinics. But there is one basic skill that is not emphasized in our training which I think is vital—cardiopulmonary resuscitation.

The American Heart Association identifies six common causes of sudden death, three of which have the potential of occuring in our pharmacies: cardiac arrests, drug reactions, and sensitivity reactions. Many of our patients have cardiac problems or seizure disorders, or suffer from "poly-pharmacy", or ask advice about bee stings. With such a great potential for something bad happening around us how can we promote public health without being prepared? How can we sell ourselves as the most seen and needed health professional without being able to help a patient in a dire situation?

We are also trying to expand our prestige in the eyes of other health professionals. How must we look when we can't perform such a simple and potentially life saving procedure?

What kind of example are we setting for our heart patients and their families? Or for new parents who should certainly be trained in CPR?

The solution is simple *and* cheap—learn CPR.

For those of you that are already CPR certified; you are to be commended for your insight and dedication to pharmacy and the public. For those of you who are not yet certified, look for details in the near future of when and where the MPLA will sponsor CPR training and recertification for all of it's members. Also, please help encourage the school of pharmacy to make CPR training a mandatory part of the education process, just like blood pressure monitoring is.

Brian T. Sanderoff
Vice Speaker
MPhA House of Delegates

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 11

Advising Consumers on OTC Antitussives and Expectorants

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. review basic information about coughs and the role of cough suppressants and expectorants;
2. discuss important information about the pharmacology and therapeutics of antitussive and expectorant medications, and suggest consumer advice;
3. present the findings of an FDA/OTC advisory panel that reviewed antitussive and expectorant drugs.

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Objectives

At the conclusion of this lesson, the participant will be able to:

1. list the Category I antitussives and expectorants;
2. state important pharmacologic and therapeutic information about cough suppressants;
3. discuss relevant patient information for correctly using these drugs; and
4. discuss the findings of the FDA/OTC advisory panel that reviewed antitussives and expectorants.

Introduction

Coughing is a symptom associated with a wide variety of respiratory disorders. It also occurs when irritants are inhaled. Coughing is a normal physiological event in that the body attempts to clear the respiratory passages of these irritants or other debris. Coughing frequently accompanies the common cold due to mucus that has accumulated within the respiratory passages as a result of viral or bacterial invasion.

Non-productive coughing may be bothersome and annoying when it interferes with an individual's comfort, rest, work or recreation. It may be severe enough to induce vomiting or exhaustion. The act of coughing sprays aerosolized mucus particles that may contain virus from the respiratory tract into the air. Thus it is also annoying to persons around them, and gives individuals the desire to control it.

This lesson examines OTC antitussives and expectorant drug products. It distinguishes between the pharmacologic actions of the two, and discusses major warnings, precautions and drug interactions that consumers should be made aware of. It also provides general patient information for correct use of these products.

Coughing

The impulse to cough may originate from within the respiratory system or from external forces. When the sensory nerve endings within the mucous membranes of the respiratory passages are stimulated, coughing ensues.

Such stimulation can result from foreign substances blocking the breathing passages, bronchoconstriction, chemical irritation, presence of retained mucus or fluids, or infection. Tickling the external ear canal is an example of an external stimulation that may induce coughing.

Productive vs. Non-Productive Coughs. A *productive* cough is a natural physiological response to remove accumulated material from the lower respiratory tract. Productive cough generally responds to increased fluid intake or to an OTC expectorant.

A *non-productive* (nuisance) cough serves no physiological function. Non-productive coughs normally require a cough suppressant product such as codeine, dextromethorphan or diphenhydramine for relief.

Antitussives

An antitussive, which is usually considered synonymous with a cough suppressant, can be either cough suppressant or expectorant. Antitussives act peripherally (e.g., local anesthetics) on sensory nerve receptors within the respiratory tract, or centrally (e.g., codeine and dextromethorphan) to suppress the medullary cough center and, consequently, raise the threshold for incoming cough impulses. This inhibits or suppresses the act of coughing

Other antitussives may enhance removal of bronchial fluids by de

TABLE 1

Antitussive and Expectorant Ingredients Classified as to Safety and Effectiveness by the FDA

Category*	Ingredient	Antitussive	Expectorant
I	Benzonatate**	X	
	Camphor ointment	X	
	Chlophedianol HCl**	X	
	Codeine; C. sulfate, C. phosphate	X	
	Dextromethorphan; D. HBr	X	
	Diphenhydramine HCl	X	
	Guaifenesin		X
	Menthol/peppermint oil (ointment, lozenge or compressed tablet)	X	
II	Antimony potassium tartrate		X
	Chloroform		X
	Hydrocodone bitartrate	X	
	Iodides		X
	Ipecac syrup and fluid extract		X
	Squill preparations		X
	Turpentine oil (spirits, oral)	X	X
III	Ammonium chloride		X
	Beechwood creosote	X	X
	Benzoin preparations (inhalant)		X
	Camphor (lozenge, topical/inhalant)	X	X
	Caramiphen edisylate	X	
	Carbetapentane citrate	X	
	Cod liver oil	X	
	Elm bark	X	X
	Ethylmorphine HCl	X	
	Eucalyptol/eucalyptus oil (ointment, lozenge, mouthwash, topical/inhalant)	X	X
	Horehound	X	
	Menthol/peppermint oil (mouthwash, topical/inhalant)	X	X
	Noscapine; N. HCl	X	
	Pine tar preparations		X
	Potassium quaiacolsulfonate		X
	Sodium citrate		X
	Terpin hydrate preparations		X
	Thymol (ointment, lozenge, room spray, mouthwash, steam inhalant)	X	
	Turpentine oil (ointment, topical/inhalant)	X	X

*Categories: I = Safe and effective; II = Unsafe and/or ineffective; III = Safe, but not yet proven effective.

**Suggested by FDA to be suitable for OTC marketing. No final decision made as of the date of publication of this article.

creasing the viscosity of retained respiratory secretions. Humidification of inspired air and/or expectorants provide such activity. Additionally, demulcents that soothe irritated throat mucosa and bronchial airway walls, and other substances that relax smooth muscle within the bronchial airway in the presence of spasm may also produce an antitussive action.

Table 1 lists cough suppressants and expectorants that have been reviewed for safety and effectiveness by an FDA/OTC advisory panel. At the time of original publication of this lesson, this listing of ingredients was at the "tentative final" stage. This means that FDA's "final" action had not been taken.

Cough Suppressants

Codeine. The narcotic codeine and its salts are effective antitussives. Codeine has remained the standard antitussive to which all others are compared.

Used as directed, codeine is not only effective, but also safe for self-administration. Oral doses rarely cause physical dependence. The potential for abuse is low. The quantity of codeine allowable in OTC cough preparations is considered C-V under the Federal Controlled Substance Act. However, its sale is currently restricted to prescription-only status in some states.

Single adult oral doses of codeine up to 20 mg are not associated with significant adverse effects. Larger doses may cause drowsiness, lightheadedness, loss of appetite, nausea, vomiting, and headache. Some people also experience abdominal discomfort and constipation when taking codeine-containing products. In fact, FDA requires a warning on the label of OTC's containing codeine that constipation may occur.

Most literature citations of codeine toxicity refer to its use as a prescription analgesic which is normally in the range of 60 to 120 mg or more every four hours. Central sedation including respiratory arrest, coma, and death have been reported in children under six years of age following single doses of 5 to 12 mg/kg.

There are no well controlled studies that have investigated the antitussive effect of codeine in children in this age group. Therefore, FDA has stated that, in its opinion, codeine should not be given to children under age six unless under the direct supervision of a physician.

Dextromethorphan. Dextromethorphan, the dextrorotatory isomer of the morphinan molecule, is neither analgesic nor addictive. This cough suppressant has been shown in clinical trials to be just as efficacious on a mg-to-mg basis as codeine. While a few medical experts question the efficacy of dextromethorphan, most agree that it is a very effective antitussive compound. Many believe it to be the ideal cough suppressant.

Adverse effects reported for dextromethorphan are rare. There is neither respiratory nor cardiovascular depression from therapeutic doses. Doses exceeding 300 mg (15 times the recommended dose) taken several times daily have, on occasion, caused bizarre behavior.

Reactions reported in children include nausea, insomnia, urticaria, and hallucinations. A review of the recent literature concerning adverse effects to dextromethorphan in children aged one to ten years indicates that the drug is safe.

Diphenhydramine Hydrochloride. The antihistamine diphenhydramine (e.g., Benadryl®, Benylin®) was initially used in the mid 1940's to relieve a wide variety of allergic symptoms. Over the years, the drug has been repeatedly shown to possess cough supressant activity ranging from 25 to 120 percent of that of codeine. Most clinical studies reveal that a 25 to 50 mg antitussive dose of diphenhydramine is equivalent to 15 mg of codeine.

Diphenhydramine acts to depress the central cough center by mechanisms similar to codeine. It also possesses anticholinergic activity which blocks efferent (outgoing) impulses from the cough center. These nerve fibers are transmitted through cholinergic pathways to the diaphragm, and to intercostal and abdominal muscles. All are involved in the coughing reflex.

Side effects from diphenhydramine are rare. The most common one is CNS sedation, with nearly 50 percent of persons taking 50 mg doses experiencing some degree of drowsiness. Lower doses, common with cough preparations, are much less likely to produce this effect.

The recommended OTC dose is 12.5 to 25 mg. Manufacturers are not permitted to market higher strengths over-the-counter at this time.

Diphenhydramine has a low potential for abuse. Because of its anticholinergic activity, the dry mouth and respiratory passages that would result from frequent or large doses limit its abuse.

Camphor, Menthol, Eucalyptus. Incorporated into a petrolatum base (i.e., Vicks VapoRub®) and applied onto the chest, camphor, eucalyptus, and menthol have long been used for their cough suppressant activity. The FDA/OTC advisory panel which studied these ingredients found insufficient evidence to suggest that they possess effective action. Since that time, however, additional clinical trials have been completed. The results indicate that camphor and menthol do indeed demonstrate cough suppressant action. They have, therefore, been classified as Category I.

Eucalyptus remains in the "needs more study" category (Category III). It appears that, if it continues to be included in cough remedies, it will probably be as a flavoring/aromatic agent.

Camphor and menthol stimulate the cold sensory receptors and produce a feeling of coolness on the respiratory tract. This causes a local anesthetic action on respiratory mucous membranes, and is probably responsible for their cough suppressant effectiveness.

The ointment product should be applied in a thin layer to the throat and chest area three times a day or as directed by a physician. The area of application can be covered with a warm, dry cloth if desired (just like grandma used to do!). This cloth, or clothing, should be left loose about the throat to enable vapors to reach the nose and mouth. The product has not yet been specifically tested for children under the age of two.

Menthol alone, in doses of 5 to 10 mg, is also used in throat lozenges and is classed as Category I for this purpose. Consumers should allow the medication to slowly dissolve in the mouth, repeating administration every hour or more as needed. Again, eucalyptus is present as an aromatic.

Expectorants

Expectorants dilute thick, tenacious secretions within the respiratory system. This facilitates their removal. OTC products containing expectorants are often used for both acute (e.g., common cold, acute bronchitis) and chronic (e.g., asthma, emphysema) conditions.

The lumen diameter of bronchioles is less than one millimeter. The mucus layer that lines these tubules is about five micrometers. During periods of chronically inflammed bronchioles, this mucus layer may increase in thickness twenty-fold to 100 micrometers or more. Therefore, a very slight spasm may cause bronchial lumen occlusion. For this reason, it is important for pharmacists to recommend that patients with chronic, recurring cough seek medical attention rather than OTC cough suppressants.

The pharmacological action for expectorants is thought to be stimulation of receptors in the gastric mucosa which enhance fluid output from secretory glands of the gastrointestinal system. This increases fluid flow from glands that line the respiratory tract.

Expectorants may also stimulate vagal nerve endings in bronchial secretory glands. Some data show that they stimulate centers within the brain which promote enhanced respiratory fluid flow.

Regardless of action, there is an increase in volume along with a decreased viscosity of bronchial secretions. This facilitates mucus removal and reduces irritation to the bronchial tissue, therefore suppressing coughing. Increased hydration and environmental relative humidity enhance their activity.

The FDA/OTC advisory panel's original report on expectorants did not include any Category I ingredients when it was published. Of the twenty ingredients evaluated as potential expectorant drugs, six were placed into Category II (banned) and the other fourteen were classified as Category III (needs more study).

Since that time, however, clinical trials on guaifenesin have been conducted and preliminary reports from FDA indicate that the drug will receive official Category I rating soon. Guaifenesin has been demonstrated by double-blind, crossover studies to be an effective expectorant.

Guaifenesin. Guaifenesin (previously called glyceryl guaiacolate) decreases sputum adhesiveness and enhances its removal in doses of 2400 mg per day. Although effectiveness is not prominent following five to seven days of therapy, some expectorant action can be anticipated following administration of several doses.

Guaifenesin is safe when taken over a wide range of doses, and adverse effects are rare. The most commonly reported ones include vomiting, nausea and gastric disturbance, and, rarely, drowsiness. Taking guaifenesin with water often reduces GI effects.

Tables 2 and 3 contain representative products that contain Category I antitussive and/or expectorant ingredients.

Combination Products

Formerly, OTC cough control products frequently contained several ingredients. Some combinations made clinical sense, and others had

TABLE 2

Representative OTC Single Ingredient Antitussive Products

Containing Dextromethorphan	
Benylin DM	10 mg/5 ml
Chloraseptic Cough	10 mg/lozenge
Congesprin	5 mg/5 ml
Creamacoat 1	10 mg/5 ml
Delsym	30 mg/5 ml
Hold	7.5 mg/lozenge
Mediquell	15 mg/lozenge
Pediacare 1	5 mg/5 ml
Pertussin 8 hour	15 mg/5 ml
Romilar CF	15 mg/5 ml
Romilar Childrens	2.5 mg/5 ml
St. Joseph Cough	7.5 mg/5 ml
Sucrets Cough	7.5 mg/lozenge
Containing Guaifenesin	
Breonesin	200 mg/capsule
Colrex	100 mg/5 ml
Creamacoat 2	100 mg/5 ml
Robitussin	100 mg/5 ml
2/G	100 mg/5 ml

little therapeutic value. The FDA/OTC advisory panel addressed the issue of combining antitussive and expectorant ingredients. The results of its report are listed in Table 4.

TABLE 4

Combinations Permitted for OTC Antitussive and Expectorant Drug Products

Antitussive + Antihistamine*
Antitussive + Antihistamine + Decongestant
Antitussive + Expectorant**
Antitussive + Decongestant
Antitussive + Local Anesthetic***
Antitussive + Expectorant + Decongestant**
Expectorant + Oral bronchodilator****
Expectorant + Decongestant

*Must be labeled, "Caution: May cause marked drowsiness"
**For treatment of non-productive cough
***Can only be formulated as a lozenge or compressed tablet for dissolution in the mouth
****Must be labeled only for cough associated with asthma

"Old Standards"

Several of the "old standard" ingredients that were once purported to exert expectorant activity such as ammonium chloride, citric acid/sodium citrate and terpin hydrate have not yet made the grade of proven effectiveness. While they are undoubtedly safe in the doses previously used, the total dose needed to exert better expectorant activity than water appears to be too great to be palatable or reasonable for pharmaceutical incorporation into cough syrups.

What's Ahead?

Chlophedianol hydrochloride (formerly available as Ulo Syrup) and **benzonatate** (available as Tessalon Perles) have both been suggested by FDA to be suitable for switching from their current prescription-only status classification to OTC status. Both substances have been available on prescription for nearly two decades, and both have been shown to be safe when used as directed. No final decision on either drug has been made, and OTC marketing will not be permitted until FDA publishes its Final Rule on OTC antitussives/expectorants.

Consumer Advice

Consumers should be reminded that coughing is a normal physiological reflex that is not intended to be totally suppressed. Whenever coughing interferes with sleep or other activities, it can be subdued when there are no contraindicating factors such as asthma.

A variety of disorders may cause coughing as a symptom. Whether a cough suppressant or expectorant should even be used depends upon the particular medical condition. Asthma and emphysema, for example, require the cough reflex to keep the respiratory passages cleared of excessive secretions. Suppressants should not be used in these cases. For self-limiting conditions such as the common cold, cough suppressant use is appropriate.

When additional symptoms (e.g., post-nasal drip) are present, appropriate products containing a combination of ingredients may be selected and recommended. In the absence of other symptoms, products containing only a cough suppressant and/or expectorant should be recommended.

Individuals taking them should be advised to drink at least eight to ten glassfuls of water daily while the cough is productive. A salt water gargle may help relieve minor throat ir-

TABLE 3

Representative OTC Combination Cough Preparations Containing Dextromethorphan and Guaifenesin

Product	Dextromethorphan* (mg)	Guaifenesin* (mg)
Cheracol DM Liquid	10 mg	100 mg
Efficol Expectorant Liquid	2.5 mg	50 mg
Kolephrin GG/DM Liquid	15 mg	150 mg
Novahistine Cough Liquid	10 mg	100 mg
Pertussin Original Liquid	3.5 mg	25 mg
Queltuss Tablets	15 mg	100 mg
Robitussin DM Liquid	15 mg	100 mg
Robitussin Cough Calmers Lozenges	7.5 mg	50 mg
Silexin Cough Liquid	5 mg	50 mg
2/G DM Liquid	15 mg	100 mg
Vick Cough Liquid	3.5 mg	25 mg

*Per 5 ml, tablet or lozenge

TABLE 5

Advice for Consumers Requesting a Cough Preparation

- Take only as directed on the label.
- Drink at least 8 to 10 glassfuls of water (or other fluids) each day while taking this product.
- Increase the relative humidity in the home.
- Ask your pharmacist for a calibrated measuring device to administer doses to children. Household spoons may differ in size.
- Consult a doctor if cough persists for more than one week, tends to recur, or is accompanied by high fever, rash or persistent headache. These may be signs of a serious condition.

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ETT SEKEL AV OMSORG

GONDOZÁS EGY ÉVSZÁZADON ÁT

قرن من الرعاية الصحية

EIN JAHRHUNDERT FORSCHUNG FÜR LEBEN UND GESUNDHEIT

STO LET PÉČE O ZDRAVÍ

YÜZYILLIK BAKIM

ศตวรรษแห่งความปลอดภัย

VUOSISATA HUOLENPITOA

ΕΝΑΣ ΑΙΩΝΑΣ ΦΡΟΝΤΙΔΑΣ

CIEN AÑOS AL CUIDADO DE LA SALUD

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STO LAT OPIEKI

СТОЛЕТИЕ МЕДИЦИНСКИХ ОБСЛУГ

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ritation and alleviate coughing. A room or whole house humidifier may be beneficial during the winter months.

Some people feel that taking cough medicine with water reduces its effectiveness. This may be true for older products that depended on demulcent activity to soothe irritated tissues. For truly effective products, water can be taken if the medication tastes badly, or if it irritates the stomach. A lot of water should definitely be taken to assist expectoration when the cough is productive.

Coughing frequently persists for several days beyond the disappearance of other common cold symptoms. Whenever a cough continues or worsens, or is still present beyond ten to fourteen days of onset of a cold, medical assistance should be sought. These may represent a more serious medical condition.

Table 5 lists important points of information for consumers requesting a cough suppressant.

Patient Aid

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

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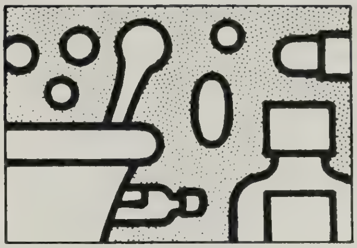
Things You Should Know FOR YOUR GOOD HEALTH



Do Yourself a Favor - Quit Smoking

Cigarette smoking is the largest preventable cause of illness and premature death.

Cigarette smoking is a major factor leading to heart disease. For years the link between cigarette smoking and lung cancer and chronic lung disease has been known. However, knowledge of the relationship between cigarette smoking and diseases of the heart and blood vessels is more recent.

Every year, nearly one million Americans die of heart attack, stroke and related disorders – greater than all other causes of death combined. And nearly 40 million Americans have some form of these diseases.

All cigarette smokers run an extra risk of heart disease. The risk is even higher if the smoker also has high blood pressure and/or high levels of fat (cholesterol) in the blood.

We do not fully understand everything about how cigarette smoking increases the risk of heart disease. We do understand the effects of both the nicotine and carbon monoxide on the heart and blood vessels.

When you smoke a cigarette, the nicotine makes the heart beat faster. As a result, the heart is forced to work harder and needs more oxygen. To make things even worse, the carbon monoxide from the tobacco smoke cuts down the amount of oxygen carried in the blood to the heart.

Hardening of the arteries is a build-up of fatty deposits on the inner walls of the arteries. This narrows the blood vessels. The heart must then work harder to pump blood through the narrowed blood vessels. This is a major cause of heart attack and stroke.

Smokers are more likely than non-smokers to have hardening of the arteries of the heart (coronary arteries) and the main artery (aorta). Also, the disease in smokers is more likely to be worse than in non-smokers.

Cigarette smoking is one of three major risk factors of heart attack. The other two are high blood pressure and high levels of fat (cholesterol) in the blood.

Persons who smoke a pack of cigarettes a day have more than twice the risk of heart attack than a person who has never smoked. And the risk for a smoker of more than a pack of cigarettes a day is three times greater.

Smokers who have a heart attack have less chance for survival than a person who does not smoke. And by continuing to smoke after a heart attack, the person's chance for a second attack increases.

No cigarettes are safe. The low tar and nicotine cigarettes are not as bad as those high in tar and nicotine. However, the risk of death by heart attack is still greater for smokers of any cigarettes than for non-smokers.

Many smokers, by switching to lower tar and nicotine cigarettes, smoke more and inhale deeper to make up for less nicotine. As a result, the smoker is exposed to more of the other harmful substances in the smoke which may increase the risk of disease.

When you stop smoking, regardless of how long or how much you have smoked, your risk of heart disease will be reduced eventually. Don't wait until you have heart disease. **Stop smoking now.**

(The above information was obtained from the American Heart Association.)

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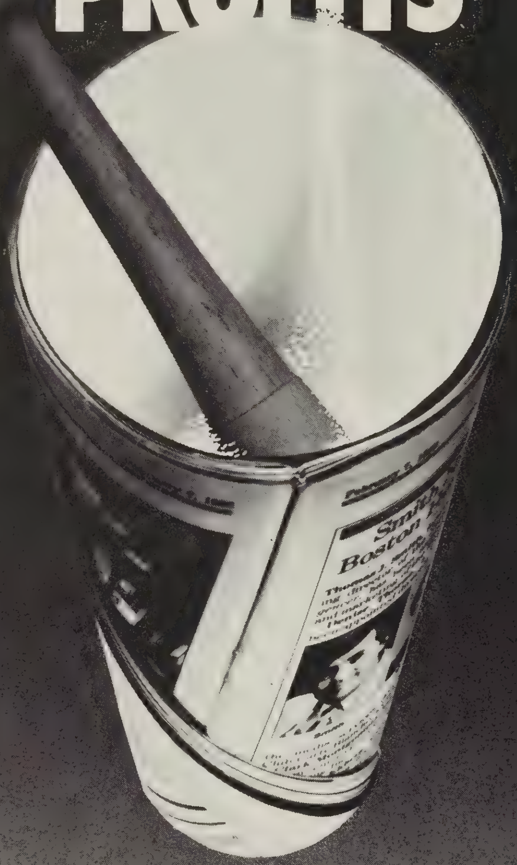

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009	Antidiarrheals (Oral)	_____
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012	Antihistamines (Oral)	_____
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033	Nitrates (Sublingual)	_____
034	Nitroglycerin (Topical)	_____
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036	Ophthalmic (Eye) Drops and Ointments	_____
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039	Potassium-sparing Diuretics and Hydrochlorothiazide (Oral)	_____
040	Potassium Supplements (Oral)	_____
041	Prazosin (Oral)	_____
042	Skeletal Muscle Relaxants (Oral)	_____
043	Sulfonamides (Oral)	_____
044	Tetracyclines (Oral)	_____
045	Thiazide Diuretics (Oral)	_____
046	Thyroid Hormones (Oral)	_____
047	Tricyclic Antidepressants (Oral)	_____
048	Xanthine Bronchodilators (Oral)	_____

Employee/Employer Relations Committee

SALARY AND BENEFITS SURVEY 1986

Richard Reitz and Dudley Demarest

The Maryland Pharmacists Association 1986 Salary and Benefits Survey of pharmacists in Maryland was performed in the spring of this year. Questionnaires were mailed to approximately 1100 members of the association in March and there were 198 respondents. The response rate of 18 percent is almost identical to the 1985 survey.

In reviewing the information provided by this survey please keep in mind that the respondents represent an interested minority of association members. This information must be used cautiously since the respondents may not be truly representative of all Maryland pharmacists. All generalizations made in this report are based on the survey and refer only to the respondents.

Let us first examine the characteristics of those who responded. The distribution of age and sex of the respondents appears in Table 1. Most of the respondents are young, about 50 percent are under 36 and have graduated from pharmacy school within the past ten years.

Perhaps the most striking observation to be drawn from this table is the growing role of females in pharmacy. Overall, females number less than a third of total respondents, but account for almost a half of those less than 35 years old.

TABLE 1
Age/Sex Profile

	Age Categories					
Sex	25–34	35–44	45–54	55–64	65+	Total (%)
Male	43	38	12	24	26	143(72)
Female	35	16	2	2	0	55(28)
Total (%)	78(39)	54(27)	14(7)	26(13)	26(13)	198(100)

Most of the respondents (75 percent) work full time. In Table 2, the respondents are separated by practice setting and we can see the average salary that is derived from each type of practice. Pharmacists who work in hospitals still have the lowest average salary of all staff level pharmacists and chain pharmacists have the highest. Pharmacists who have made their careers outside of traditional practice are reporting the highest average salaries overall.

In the 15 month period between surveys the average salary of all respondents increased by 7.9 percent. The average salaries for staff level pharmacists increased in this period from $31,347 to $34,696 or 10.7 percent. The gap between hospital pharmacists and chain pharmacists narrowed; hospital pharmacist salaries increased at almost twice the rate of other staff level pharmacists. The average salaries for retail managers increased 7.0 percent.

TABLE 2
Practice Setting and Average Salary (1986 and 1985)

Practice setting	Number of responses (%)	# Full time	1985 Ave salary	1986 Ave salary	Percent change
Staff–Hosp	22(11)	18	$27,071	$31,111	14.9
Staff–Indep	57(30)	32	30,667	32,968	7.5
Staff–Chain	55(28)	46	34,045	36,956	8.6
Staff-HMO	6(3)	3	—	40,000	—
Mgr–Retail	42(22)	40	38,452	41,125	7.0
Mgr-Hosp	4(2)	4	41,480	41,250	0†
Sales rep	2(1)	2	28,000	45,000	60.7†
Other	5(3)	3	41,543	48,333	16.3
Total	193(100)	148	33,786*	37,027*	7.9

* Weighted average salary of all respondents

† Inconsistencies in salary differences may be due to small sample sizes

There were 50 respondents (25 percent of the total) who mainly worked part time. Their part time wages ranged from $8.00 to $26.00 and averaged $14.25 per hour. This is a 5.2 percent increase over the 1985 average of $13.54.

The distribution of salaries was compared to years since graduation and length of employment in Tables 3 and 4. Although half of these respondents have been out of pharmacy school more than ten years, only 17% have stayed at one position more than ten years. Thus, job loyalty is not a common characteristic among these respondents. This may be due, however, to the apparent resistance of employers to reward experience or job longevity.

TABLE 3
Salary and Years Since Graduation

Salary range	Years since graduation <5	5–10	10–15	15–20	>20	Total
<30	6	1	1		4	12
30–35	7	5	7	1	6	26
35–40	21	14	7	3	10	55
40–45	6	8	3	2	10	29
45–50		1	6	1	3	11
>50	1	3	1	5	5	15
Total (%)	41(28)	32(22)	25(17)	12(8)	38(26)	148(100)
Ave sal	33K	37K	37K	45K	38K	37K

TABLE 4
Salary and Length of Employment

Salary range	Length of Employment (Years) <5	5–10	10–15	15–20	>20	Total
<30	10	2				12
30–35	18	6	1		1	26
35–40	39	11	4		1	55
40–45	18	5	3		3	29
45–50	3	4	2	1	1	11
>50	5	2	3	4	1	15
Total (%)	93(63)	30(20)	13(9)	5(3)	7(5)	148(100)
Ave sal	35K	37K	42K	59K	40K	37K

The criteria for salary increases of employee pharmacists are presented in Table 5. It may be surprising to note that almost one fourth of these pharmacists do not receive regular salary increases. (However, this figure also corresponds to the number of pharmacists who work mainly part time).

TABLE 5
Criteria for Salary Increase

	# Resp	(%)*
Yearly review	86	(43)
Automatic	49	(24)
Sporadic	48	(24)
Performance	48	(24)
Cost of living	40	(20)
Contracted	11	(5)

* Respondents checked ALL appropriate answers

TABLE 6
Employee Pharmacist Benefits

	# Resp	(%)*
Paid vacation	162	(84)
Paid holidays	147	(79)
Paid sick leave	132	(70)
Health insurance	151	(80)
Life insurance	116	(61)
Liability insurance	113	(60)
Disability insurance	107	(56)
Discounts on purchases	119	(63)
Pension	94	(50)
Bonus	76	(40)
Profit sharing	55	(30)
Overtime available	107	(62)
Overtime mandatory	22	(16)
Uniforms required	105	(61)
Uniforms provided	99	(57)
State dues paid	55	(27)
Local dues paid	31	(15)
National dues paid	17	(8)
CE registration	32	(16)
CE time paid	29	(14)
CE room & board	15	(7)
CE travel expenses	15	(7)

* Percent based on total number of responses

The distribution of benefits for employee pharmacists is presented in Table 6. When you review the distribution of benefits, please bear in mind that about one quarter of the respondents work mainly part time and may not be expected to receive a full range of benefits.

The majority of respondents received paid vacation time, averaging 1.6 weeks after one year of employment, 2.1 weeks after two years and 2.6 weeks after five years. Also, most respondents received paid holidays and sick time, averaging more than seven holidays and almost 16 sick days per year.

A large majority of respondents receive health insurance of which at least 50 percent of the cost is paid by the employer. Almost two thirds of these also receive family coverage. More than half of the respondents also receive disability, life and professional liability coverage.

Other benefits, including profit sharing, bonuses, pensions and discounts on store purchases, are offered to substantial numbers (30 to 63 percent) of respondents. However, employers are less inclined to provide for the professional growth of their pharmacists. Only 27 percent of the respondents reported that (state) professional association dues are paid by their employers. Less than 16 percent are reimbursed for continuing education activities.

Working conditions are explored in Table 7. About two thirds of the respondents found their supervisor and employee relationships to be good or excellent. About two thirds of the respondents reported that the conditions, morale and location of their workplace were good or excellent. This implies that the majority of these pharmacists are happy with these aspects of their working conditions.

TABLE 7
Working Conditions

	Exc*	Good	Fair	Poor
Employee/supervisor relationship	39	45	11	5
Employee/employee relationship	30	53	12	5
Physical working conditions	21	51	22	6
Morale	24	40	26	10
Workplace location	28	46	20	6

* Percent of total responses

$$$$$$$$

Pharmacy Case Management as a Tool to Serve the Frail Elderly

by Lucinda L. Maine, B.S., Ph.D.

Understanding geriatric pharmacotherapy is similar to the parable of the blind man and the elephant. The perception one derives is directly related to the part of the elephant one touches first. In the realm of geriatric drug use sweeping generalizations of the drug use problems aged people face and solutions to those problems may fall short of a goal of improving geriatric drug therapy in a given pharmacist's service area. This article will present a picture of geriatric pharmacotherapy which reflects the heterogeneity of older adults and suggests strategies for improving drug use in the segment of the aged population where improvements are most needed, notably the frail elderly.

Geriatric Drug Use Patterns

Many of the perceptions pharmacists and other health professionals hold relative to geriatric drug use have come from exposure to older patients in longterm care settings. The excessive prescription of drugs used to treat the more disabled patients in nursing homes, including potentially toxic cardiovascular and psychotropic drugs, came under scrutiny in the late 1960's and early 1970's. The Department of Health, Education and Welfare, now Health and Human Services, enacted a drug regimen review regulation in 1974. (1) Depending on the patients' levels of care (i.e. skilled or intermediate) a pharmacist or a nurse must review the medical record and pertinent data for each nursing home patient on a monthly basis. Over the past decade the effectiveness of consultant pharmacists' activities in longterm care has been examined by several investigators.[2,3] Most notably, Thompson and colleagues found that pharmacists can have a profound impact on the health status, cost of health care and even mortality rate for nursing home residents when the pharmacist assumes the role of primary care provider (i.e. prescribing and monitoring drug therapy, rendering general care) for these patients.

The older individuals residing in the community, as a group, differ markedly from nursing home residents. Several studies of the drug use patterns of noninstitutionalized aged people show very consistent patterns of prescription and nonprescription drug utilization among community-living samples chosen from a variety of different areas of the United States. To characterize these patterns of drug use, 25 to 30 percent of individuals studied reported no prescription drug use at the time of the investigation. Approximately half of those older people sampled reported the use of 1 to 3 prescription products concurrently, and the balance, perhaps 15 to 25 percent of the ambulatory elderly population, use four or more prescription drugs on a regular basis.[5,6,7]

Nonprescription drug use is more widespread among older people when compared to younger populations and this includes the common reliance on aspirin-containing products and laxatives. The majority of older adults use at least one nonprescription drug regularly. Many of them use one or more vitamin products daily.[8]

Patterns of drug use among the older population are important for at least two reasons. First, studies have demonstrated that the incidence of adverse effects from medications increases markedly as the number of drugs a person takes increases. Other risks from drug therapy, most notably drug-induced hospital and nursing home admissions, are also higher for those patients taking several drugs concurrently.[9] The other point is that recognizing that it is only a limited segment of the geriatric population that need special attention to improve their drug use makes the problem of geriatric drug therapy more manageable for patients, professionals and caregivers.

A Model of Risk

Fedder and Lamy have proposed a model for the identification of those individuals whose drug therapy places them at a higher risk of negative health consequences compared with other older people.[10] The "Index of Risk" is presented in Table 1. Research has shown that the best single determinant of risk is the number of prescription drugs an individual must manage.[11,12] The number of drugs that can be used as a threshold value for the detection of high risk patients appears to be 4. The other model variables can modify the level of risk in both positive and negative directions. This can best be demonstrated by using a case study.

A Positive Geriatric Drug Use Case

G.K. is an 81 year old female residing alone in her own home in an Eastern city. She has recently been

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Table 1
Index of Risk

Characteristics	Risk
Age	The older the patient, the greater the drug errors and ADR's
Gender	Females are more susceptible to ADR's
Socioeconomic Status	Education, occupation and income impact on drug use
Social Support	Lack of family and friends can lead to isolation and poor health behavior
Living Arrangement	Older adults living alone may lack the social support needed for medication management
Multiple pathology, drugs	Multiple pathology may demand the use of multiple drugs leading to confusion and possible errors
Multiple providers	Multiple providers can lead to unclear communications, fragmented services, overlapping therapies
Sensory, mental impairment	Impaired vision, hearing or cognition can lead to inability to follow verbal or written instructions
Level of disability	Severe limitation in mobility, etc can cause multiple drug use problems

released from the hospital after an episode of decompensated CHF and is receiving services from the city's visiting nurse agency for follow-up care. Her medical history includes diagnoses of congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), transient ischemic attacks (TIA's), atrial fibrillation, arthritis, and atherosclerotic cardiovascular disease. Her medication regimen is listed in Table 2. Her therapy includes at least 17 dosing units per day. Total drug costs, paid out-of-pocket, exceed $100 monthly.

Table 2
Case Medication Regimen

Chronic Drugs:	
*Quinidine 324 mg	one tablet t.i.d.
*TheoDur 200 mg	one tablet b.i.d.
NitroDur 10 cm	one patch daily
Inderal 10 mg	one tablet b.i.d.
*Lanoxin 0.125 mg	half tablet daily
*Lasix 40 mg	2 tablets daily
*K-Lyte 25 mEq	one tablet daily
Dipyridamole 50 mg	one tablet t.i.d.
Aspirin 325 mg	one tablet daily
Diprosone Cr. .05%	apply b.i.d.

* drugs with narrow therapeutic margin

Home visits were made by the VNA's consultant pharmacist to assess the ability of this patient to manage her drug therapy. An extraordinary social network of information (i.e. voluntary) caregivers was operating to support this frail elderly patient. The pharmacy provider for G.K. is her nephew who organizes a week's supply of medications in a 4 by 7 compartment pill-minder. He also monitors compliance and refills the medications when needed. Other children, grandchildren, friends and neighbors visit or call frequently to reinforce not only medication compliance but proper nutrition and other activities of daily living.

G.K. does not know the names or purposes of her medications as she is satisfied that her "doctor and pharmacist take care of that" for her. She does transfer each day's supply of medications into a separate pill container which she keeps with her continuously. Her dosing schedule is arranged to coincide with meals and bedtime, daily routines she follows consistently.

Ideally this individual would have mastered the knowledge of her drug names and purposes with the reinforcement of her health care providers, but this is not a realistic goal for all older people. This case does underscore several critical points that warrant reinforcement. Older patients are capable of managing complex but rational drug regimens for the control of multiple chronic conditions. The "average" older person is afflicted with 3 to 4 diseases and these are usually controlled with drug therapy.

The second point is that this individual requires the commitment of a large number of people to help maintain her independence. She is a fragile patient with potentially toxic drug therapy. Mismanagement of only one or two days' therapy could result in an additional hospital admission and ultimately nursing home placement if the patient is unable to control her diseases. Mental or sensory impairment in this case would certainly undermine her independence.

Pharmacy Case Management

The role of the pharmacist in the case presented above was defined by a familial relationship. A more general role for the pharmacist in assisting frail elderly patients in the community has been labeled pharmacy case management (PCM).[13] The principles of PCM do not differ significantly from those in longterm care consulting practice but some of the practical issues are different. Identification and referral of patients, access to adequate information for decision-making and payment for services are important issues that present obstacles to the development of marketable services. Despite the obstacles, the need for case management services for drug therapy exists and pharmacists are the professionals with the skills needed to perform the case management services. A brief discussion of each of the points mentioned as limitations may serve as a stimulus for creative thought among pharmacists interested in providing services for frail elderly patients living in the community.

Many pharmacists may think it is odd to list identification of frail patients and referral to services as an obstacle to pharmacy case management. In the daily operation of community pharmacies patients who require several concurrent prescription products seek refills, call with questions and ask for the assistance of the pharmacist for delivery of prescriptions, over-the-counter drugs and miscellaneous other products. Pharmacists are also aware of patients who are hospitalized and then discharged back into the community for convalescence. The question is, which of these people would benefit from additional pharmacist intervention to increase patient and family understanding of the drug regimen, detect adverse drug reactions and to help organize the drug regimen around normal daily activities of the patient? Believing that someone else has assumed that patient care and education responsibility may be a dangerous oversight.

Two mechanisms of matching needs to services might be effective. The first is self-referral, either directly by the patient or indirectly by a family member. The second is professional referral by a home care provider, hospital discharge personnel or a physician. Each of these referral sources need one piece of information to make the contact with the pharmacist—they must know that the pharmacy provider is willing to provide the pharmacy case management service. An active marketing effort on even a small scale can alert others to the services pharmacists can provide to the patients that use their pharmacy distribution services. An amazing number of lay and professional people have a geriatric drug story that they will share with little provocation. The case may involve their mother, neighbor, sister or friend, but the story is always the same. Someone has stored old meds, become confused about the current drug regimen and had an adverse drug incident. The public is well aware of the problem of geriatric drug use but does not know the solution.

One of the most serious underlying factors in the geriatric drug use dilemma is the absence of reliable drug profiles for older patients. Medical records in physicians' offices and clinics rarely contain accurate medication histories. Too often physicians try to carry patient drug information in their head or ask older patients at each visit to recite their drug regimen. Patients sometimes carry drug lists on scraps of paper and file cards. Multiple prescribers for individual patients are truly at a disadvantage when they try to diagnose and prescribe without the benefit of a complete drug history.

The pharmacist who maintains a complete patient profile for patients has one of the most reliable drug records, at least for those patients who use only one pharmacy. Studies have recorded a high "loyalty" rate for older patients, with 85% or more elderly respondents indicating that they use only one pharmacy provider (14). Pharmacists provide copies of drug profiles frequently for patients to send to insurance companies. It seems a logical extension of that service to provide a copy of the profile for a patient's physician at the patient's request.

The pharmacist also needs more information to accurately assess the rationality of drug therapy. Diagnoses, allergies and dosage changes are often not readily available unless the pharmacist specifically requests the information.

One critical point of time when new drug information is needed by patients and providers is at discharge from hospitals and nursing homes. Frequently drugs and doses are changed during institutionalization. Patient confusion is common. One suggestion for fortifying the pharmacist to better serve patients as they return home and to the community pharmacy is to have discharge planners or other hospital personnel, the physician or the patient provide a copy of discharge orders to the primary pharmacy provider. It would then be clear as to which drugs were discontinued and which are to be taken currently by the patient. Home health care nurses are another potential source of information for pharmacists, as well as a source of questions.

The question of reimbursement for pharmacy case management services is usually reserved for the very end of such discussions and carries a consistent, negative message. Payment for these services is still the exception rather than accepted practice. There is some expectation that pharmacists should provide some of these services for consistent patrons in the course of normal patient care. To the extent that this enhances the image of the pharmacy and pharmacist this is arguably true. However extra consultation time, possibly extending to home visits, and interaction with additional health care providers must be reimbursed to be sustained. The problem today is that no one has the incentive to pay for services designed to keep older patients out of hospitals and nursing homes.

The incentives are changing in the senior population given that forty percent of the Minneapolis and St. Paul metropolitan area seniors are now enrolled in prepaid health programs supported by Medicare. The HMO's accept the risk for providing comprehensive care for elderly patients and are aware of the importance of appropriate medication management to the functional well-being of these enrollees. Mismanaged drug regimens result in hospital and nursing home admissions that can be avoided if pharmacy services are appropriately applied.

Home care providers, by Medicare regulation, are responsible for management of agency patients' drug regimens. Home care nurses have great skills for devising aids (i.e. pill-minders, egg cartons, calendars) for patients with complex and confusing drug therapies. They lack, as a rule, the knowledge to make judgements on the rationality of drug therapy and provide adequate patient education. Reimbursement for consultant pharmacy services is an allowable expense for a home care agency reimbursed by Medicare.

Reimbursement for pharmacy case management is often cited as the most prominent obstacle to providing services to patients. Yet the most direct reimbursement strategy has rarely been tested. A pharmacist has skills that can be critical to the maintenance of patients' independence. That is a marketable commodity both to the patients and their responsible caregivers (i.e. spouse, children).

Pharmacy case management is an extension of the unique skills pharmacists possess applied, in most cases, to frail elderly patients dependent on complex drug regimens for the management of chronic ailments. Reasonably surmountable barriers to information and reimbursement should not deter pharmacists from matching their unique abilities to those patients who might be placed in a nursing home due to the loss of their ability to manage their medications and live independently.

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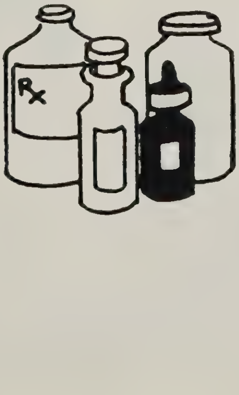

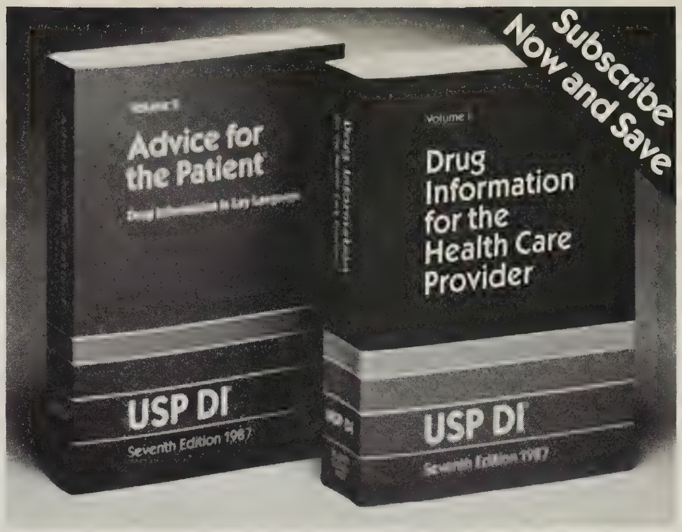

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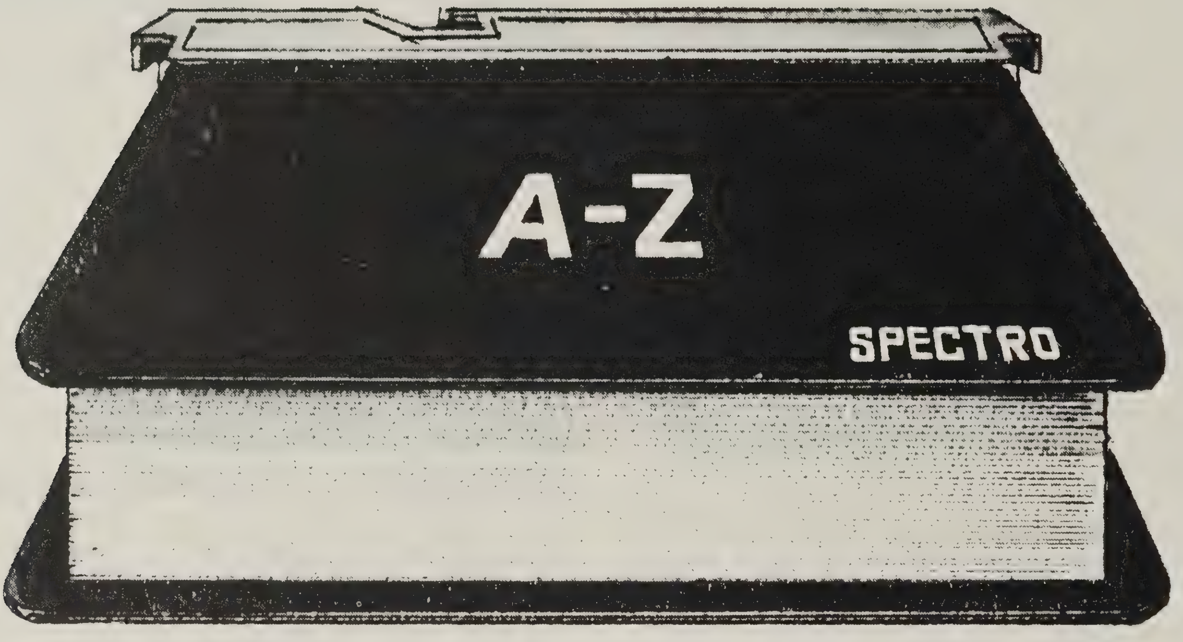

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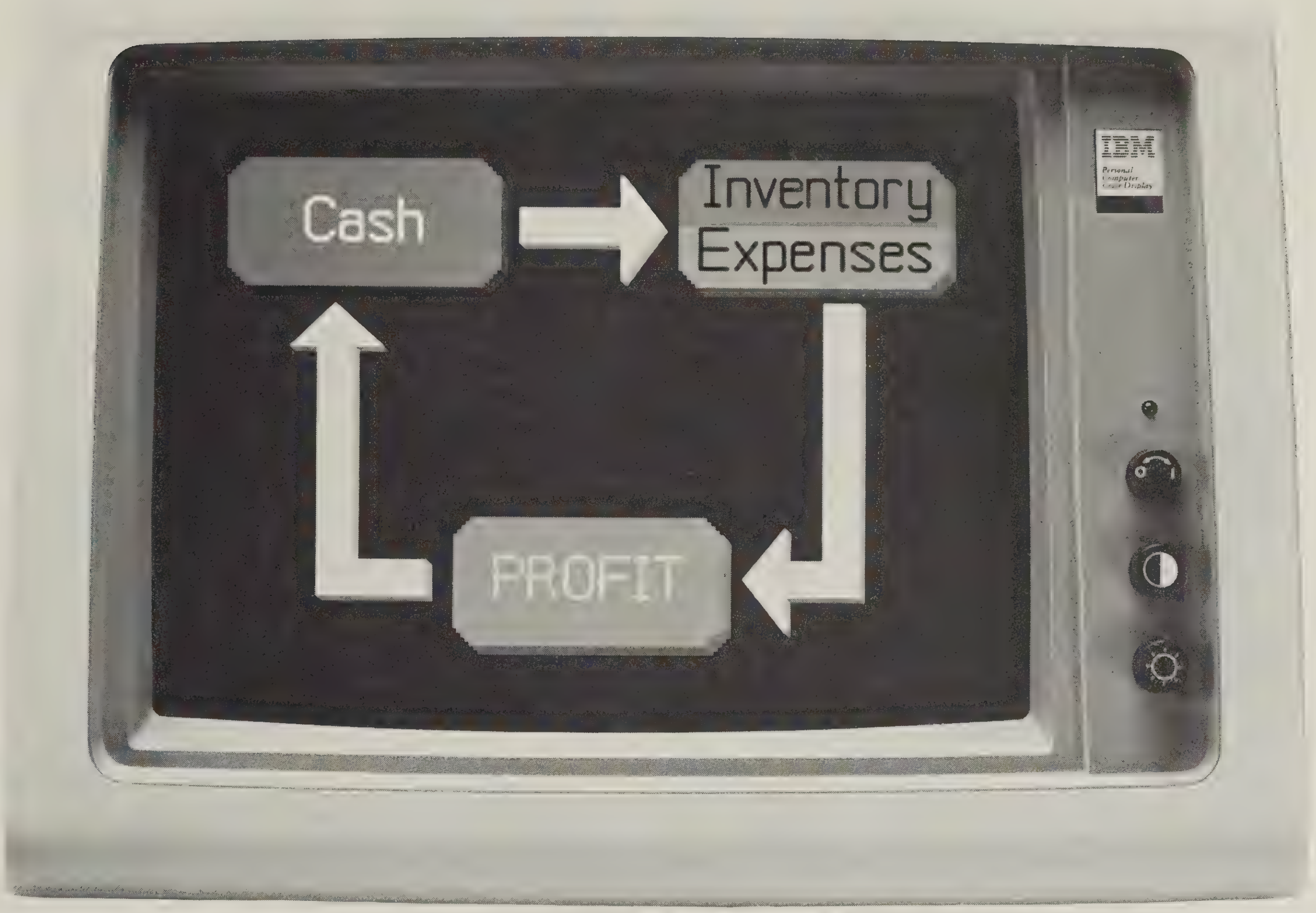

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NSAID-INDUCED GASTROINTESTINAL EFFECTS: RISK TO THE ELDERLY

by Peter P. Lamy, PhD

AGE- AND DISEASE-ASSOCIATED G.I. RISK IN THE ELDERLY

While the anatomical and physiologic integrity of the gastrointestinal tract is usually maintained into the ninth decade, elderly admitted to hospitals have more GI disorders than the general population. Vulnerability to GI problems increases with age, due to morphologic and functional changes, as well as behavioral changes and the GI consequences of multiple drug use.

The Aging Stomach: Primary and secondary age changes heighten the risk of elderly to GI problems (Table I, II). Aging is associated with secretory and morphologic changes in the stomach. After age 50, about 80% of stomachs show muscular atrophy, thinning of gastric mucosa, and infiltration of the submucosa with elastic fibers. The cumulative effect of surface injury and repair leads to atrophy of the mucosa. Accelerated and sustained cell turnover and shortening of the period of maturity of differentiated cells are responsible for reduced secretion of protective mucus. Intestinal blood flow may be reduced by as much as 50% by age 65, being further diminished by stress, CHF, hypoxia and hypovolemia. This can induce ischemia and subsequent arterial occlusion and mesenteric vascular insufficiency may often be related to GI complaints. Of major importance in community-living elderly is the influence of psychosomatic and behavioral factors. Tension, fear of disease and death, depressive illness, anxiety and worry influence stomach motility and secretory function, but habitual use of laxatives and improper eating habits also play a major part.

Chronic gastritis, irritable colon, spastic colitis, heartburn, ulcer-like distress, and nausea can result. In one study of 300 elderly, 31% suffered from these problems.

Altered Secretory Function: Gastric secretion declines with age. There is a decrease in gastric cell function, and an elevation of gastric pH. In one study, the secretory volume in those 61 to 70 years of age was only 50% and the concentration of gastric acid only 30% compared to people 21 to 30 years old. In another study, among those 60 years old and older, 43% of males and 36% of females exhibited basal achlorhydria. After stimulation, achlorhydria was still observed in 21% of males and 10% of females. Furthermore, gastric secretion is diminished in diabetes mellitus and untreated hyper- and hypothyroidism. Some elderly maintain a normal and even high acid secretory function, and duodenal ulceration in those older than 70 years may occur because acid secretion is high.

Altered Motor Function: Gastric emptying (GE) is about 2.5 times faster in younger than in older persons, because GE is under control of the CNS which may lose efficiency with advancing age. Slowing follows a reduction in gastric acid secretion, and GE is also negatively affected by stress, lack of ambulation, gastric ulcer, intestinal obstruction, myocardial infarction, and diabetes mellitus. Some drugs also delay GE, among them the anticholinergics, ganglionic blockers, isoniazid, lithium, antacids, and narcotic analgesics. GE is delayed by fatty meals in elderly more so than in younger persons.

Consequences of Changes: In elderly hospitalized patients, 25% suffered from peptic ulcer disease, 25% from neoplasm of the GI tract, and 8% from hiatal hernia. Among community-living elderly, peptic ulcer disease was present in 12%, inflammatory bowel disease in 12%, and hiatal hernia in 8%. About one-third of duodenal ulcer patients are 60 years or older and up to 20% of those 70 to 79 years suffer from chronic peptic ulcer. Ulcer disease in the elderly is more virulent and has a higher mortality rate than in the young. Gastritis increases with age, particularly in males. Atrophic gastritis changes were found in 40% of complaint-free patients 60 years and older, with a variable degree of inflammation and atrophy. It is more diffuse and shows a reduction in the number of chief and parietal cells in the mucosa. The capacity of the mucosa to secrete acid is

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TABLE I
Changes in Elderly that Increase Risk to GI Effects of NSAIDs

Change	Possible Consequences
Primary Age Change	
Morphologic change: Decreased mucosal wall thickness, mucosal blood flow	Devitalization of mucosa, atrophic gastritis, greater risk for ulcers
Motor change: Delayed gastroc emptying (?)	Longer residence time for erosive agents
Secretory change: Less and less concentrated gastric acid secretion (approx. 30% of elderly anacidic or hypochlorhydric ?)	Less resistance to injury Less rapid repair Less incidence of ulcers
Secondary Age Change	
Increased polypathology, increased use of gastric erosive drugs in management of pathology	Increased risk to injury
Tertiary Age Change	
Behavioral changes with age	30% of all GI complaints of elderly are induced by fear and anxiety

then progressively reduced. Symptoms are either absent or non-specific. Bleeding is a fairly common complication of ulcers in the elderly. Fifteen to 20% of GI bleeding in the elderly is caused by acute ulcers or erosions. Complications rise from 31% for those 60 to 64 years old to 76% for those 70 to 79 years old. Rebleeding may occur in up to 40% of elderly patients. Mortality reaches 25% in those 80 years and older. Physical signs of major GI hemorrhage in the elderly are often unreliable. The older the GI bleeder, the more likely will the patient have slcerotic vessels and impaired homeostasis, increasing the risk of hemorrhage. Subclinical malnutrition of vitamin C is often found in the elderly, and deficient ascorbic acid levels can prolong gastric bleeding.

THE PROSTAGLANDINS

Prostaglandins are present in most tissues and fluids throughout the body. Not only are they involved in the inflammatory process, but they also have a protective role in maintaining the integrity of the gastric mucosa. This involves various mechanisms, including the regulation of gastric secretion, both directly and indirectly, maintenance of the mucus-bicarbonate barrier, and mediation of gastric mucosal cell vasodilation.

The widespread use of NSAIDs is accompanied by varying degrees of GI intolerance. Elderly patients with rheumatoid arthritis often develop gastric ulcers or erosions when they receive long-term NSAID therapy. Erosive gastritis is a frequent finding. GI symptoms are due partly to the effects of NSAIDs on the gastric mucosa as observed by gastroscopic examinations. Increased gastric vulnerability is most likely caused by a systemic effect of the NSAIDs via inhibition of prostaglandin synthesis which may be selective *in vivo* in different tissues and by inhibition of gastric acid secretion.

TABLE II
Some Reasons for Increased GI Risk:

1. Intestinal blood flow diminished by 50%. Ischemia and occlusion. Damage in ischemic areas.
2. Gastric secretory volume may decrease by 50%.
3. Increased incidence of gastritis and gastric ulcers.
4. Ulcer disease more virulent in elderly. Gastric hemorrhage from superficial lesions most life-threatening. May present silently. Most at risk: older females, receiving diuretics.
5. Complications rise from 31% (60–64) to 75% (70–79).
6. Re-bleeding in as many as 40% of elderly.
7. Mortality: 25% in those 85 yrs and over.

As far as the elderly are concerned, other factors may play an important role. Local ischemia caused by atherosclerosis may predispose them to ulcer formation, an effect that may be heightened by the prostaglandin inhibition of NSAIDs which further reduces gastric mucosal blood flow. Furthermore, estrogens and progestogens increase mucus production in the stomach and post-menopausal women may therefore have a lessened mucus production, which could be further reduced by the action of the NSAIDs.

The Elderly, the NSAIDs and GI Problems: Some of the side effects of the NSAIDs, including GI problems, are inevitably associated with the particular properties of these drugs, i.e. the inhibition of prostaglandin biosynthesis. Chronic NSAID therapy is often related to gastrointestinal disorders in the elderly and the incidence of new cases of peptic ulcer is high, particularly in the elderly. Death from peptic ulcer occurs predominantly in late life. It has been estimated that the relative risk of an older patient taking an NSAID of developing an ulcer is 4.5 times that of a person not using one of these drugs, but the risk for each individual drug has not yet been identified. Apparently, the gastric mucosa is even affected, though to a lesser degree, by the newer pro-drugs (sulindac, fenbufen) since their prostaglandin inhibiting effect is systemic, and the newer NSAIDs, while possibly associated with less fecal blood loss and less endoscopically demonstrable damage still are associated with gastrointestinal bleeding. The incidence may be rarer than with aspirin or some of the older NSAIDs, but potentially life-threatening instances of clinically overt bleeding are still reported, to which females are more prone than males.

A recent study showed a significant relationship between NSAID consumption and upper GI bleeding in elderly patients admitted to a hospital. Gastric ulcer was involved in 24% of patients, duodenal ulcer in 21%, and esophagitis in 12%. In a similar study involving patients 55 years or older, gastric ulcer was the most common cause of bleeding in 29% of patients, duodenal ulcer in 21%, hemorrhagic gastritis in 17%, and esophagitis in 14%. A retrospective study of elderly patients selected for gastroscopy showed a significant association between UGI pathology and NSAID ingestion. In a prospective gastroscopic study of the effects of NSAIDs, it was shown that all NSAIDs cause gastric lesions in about 30% of all patients, the incidence rising about 2.5 times when more than one drug was used. In the UK, there has been an increase in prescribing of NSAIDs to all age groups, yet the percentage of patients with perforations taking NSAIDs only increased in those 65 years old and older. In a retrospective study comparing 269 patients with perforated ulceration and 269 age/sex matched controls, a highly significant association between age and perforations was found for those 65 years and older, but not for those younger than that. Furthermore, a highly statistically significant correlation between the annual number of patients aged over 65 with perforated ulcers taking NSAIDs and the annual number of prescriptions issued for these drugs in the region was shown. No such correlation was found for patients under 65 years. The largest number of patients were women over 65, and it was suggested that elderly, especially elderly women, are unduly susceptible to NSAID associated peptic ulcer perforation.

Chronic iron deficiency anemia may be caused by a slow but steady blood loss, resulting from diffuse gastritis and it is noteworthy that the NSAIDs cause microbleeding even in healthy normal males. Hemorrhage can occur, which can be life-threatening. The danger is most acute when the NSAIDs antiplatelet effects are combined with pre-existing coagulation effects and a high frequency of erosive gastritis. There may also be an association between lower bowel disease and NSAIDs, and unmasking of idiopathic inflammatory bowel disease, which is fairly frequent among the elderly.

Clearly, the NSAIDs are a significant cause of gastric lesions in the elderly, in whom the danger is particularly threatening, since there is often no relation between subjective symptoms and endoscopic findings.

All NSAIDs can cause gastritis for which the elderly, more than likely taking a host of drugs with erosive capabilities (Table III), are at great risk. Gastric hemorrhage from superficial lesions is the most life-threatening ADR of the NSAIDs, but peptic ulceration and perforation also occur. The majority of NSAID-induced ulcers occur in elderly women, in whom it is a significant problem. Those on concurrent diuretic therapy are most likely to develop a giant ulcer and need a blood transfusion. NSAID consumption by old patients places them at considerable risk of upper GI bleeding in which old age is an important adverse prognostic factor.

TABLE III
Drugs That Can Cause Gastric Erosion

Alcohol	Chemotherapeutics
Anticoagulants	Corticosteroids
Antimalarials	Nonsteroidals (Rx and OTC)
Antimetabolites	Potassium supplement
Aspirin	Reserpine
Ascorbic Acid	

SOME ATTEMPTS TO OVERCOME GI EFFECTS OF NSAIDs

The risk of GI involvement apparently increases in the presence of some rheumatic diseases, as the patient gets older, and as the length of the disease process extends. Thus, a host of efforts has been expended to decrease that risk. Aspirin has been formulated in a buffered form and as an enteric-coated form, but in some studies, the prevalence of duodenal lesions was the same in patients taking regular, buffered, or enteric-coated aspirin and many patients receiving enteric-coated aspirin still complain of gastric intolerance. Aspirin has also been formulated in pH-dependent and time-dependent release dosage forms. While bleeding provoked with the pH-dependent formula was less than with the time-dependent formula, bleeding still occurred. Both indomethacin capsules and suppositories cause an equal amount of gastric damage, indicating that the irritative effect of this drug on the gastric mucosa is not a local effect. Attempts to incorporate one of the NSAIDs into an "osmotic pump" had to be aborted. While this dosage form decreased overall side effects in elderly, it increased adverse GI effects.

Two pro-drugs (sulindac, fenbufen) have been developed. A pro-drug is absorbed in an inactive state through the GI tract, thus minimizing the danger of adverse GI effects theoretically. Following absorption, these drugs are transported to the liver, where they are metabolized to the active component or components, which are later themselves metabolized. However, as has been previously shown, GI effects are not completely eradicated.

Suggestions have been made that histamine H2 antagonists could be given concurrently with NSAIDs. However, there has taken place a shift in emphasis in the treatment of GI bleeding and peptic ulcers. It is now believed that total suppression of acid secretion is, indeed, undesirable, since it might predispose patients to a higher incidence of gastric carcinoma. Nevertheless, cimetidine has been used in the prevention and treatment of NSAID-induced GI effects. There are claims that the histamine H2 antagonists heal peptic ulcers despite continued use of NSAIDs. It has also been suggested that a more efficient reduction of nocturnal acid secretion might be therapeutically more important. In one endoscopic study, cimetidine was not useful in healing peptic ulcers when anti-inflammatory drugs were continued and the use of the cimetidine does not appear to protect against perforation of peptic ulcers in patients receiving NSAIDs. In any case, the safety and cost implications of long-term use of these drugs still need to be carefully considered.

Perhaps other mucosal protective agents, which may prove to be simpler and safer, ought to be considered. Prostaglandins, mucoprotectants and anticholinergic agents have been suggested, but studies need to take into consideration that the size of the ulcer to be treated is of major importance. It is significant as a predictor of healing. Those 0.5 cm in size or less have a 90% healing rate in six weeks, but those 1 cm or larger are difficult to manage and may not heal.

Many prostaglandins are in various stages of development and have been suggested as effective cytoprotective agents. A still different approach is based on the fact that NSAIDs induce micro-bleeding. Perhaps that is the reason why a new bioflavonoid, meciadanol, appears to be effective in the management of GI bleeding, since it maintains vascular integrity and protects gastric mucosal blood flow.

Lilly Digest Results for Area Pharmacies

LILLY DIGEST AVERAGES OF SELECTED OPERATING STATISTICS

AVERAGES PER PHARMACY	1985 *SOUTH ATLANTIC REGION* (205 Pharmacies)	1984 *SOUTH ATLANTIC REGION* (184 Pharmacies)	1985 Average *UNITED STATES* (1,378 Pharmacies)
SALES			
Prescription	$366,345— 66.1%	$337,175— 66.0%	$369,595— 62.2%
Other	188,064— 33.9%	173,618— 34.0%	224,323— 37.8%
Total Sales	$554,409—100.0%	$510,793—100.0%	$593,918—100.0%
COST OF GOODS SOLD	370,041— 66.7%	339,313— 66.4%	400,255— 67.4%
GROSS MARGIN	$184,368— 33.3%	$171,480— 33.6%	$193,663— 32.6%
EXPENSES			
Proprietor's or Manager's salary	$ 35,977— 6.5%	$ 33,374— 6.5%	$ 35,196— 5.9%
Employees' Wages	56,818— 10.2%	52,986— 10.4%	60,316— 10.2%
Rent	12,182— 2.2%	10,738— 2.1%	14,166— 2.4%
Miscellaneous Operating Expenses	59,850— 10.9%	54,726— 10.7%	67,422— 11.3%
Total Expenses	$164,827— 29.8%	$151,824— 29.7%	$177,100— 29.8%
NET PROFIT (before taxes)	$ 19,541— 3.5%	$ 19,656— 3.9%	$ 16,563— 2.8%
Add proprietor's withdrawal	35,977— 6.5%	33,374— 6.5%	35,196— 5.9%
TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit)	$ 55,518— 10.0%	$ 53,030— 10.4%	$ 51,759— 8.7%
VALUE OF INVENTORY AT COST AND AS A PERCENT OF SALES			
Prescription	$ 38,810— 10.6%	$ 35,781— 10.6%	$ 38,939— 10.5%
Other	38,795— 20.6%	37,736— 21.7%	49,375— 22.0%
Total Inventory	$ 77,605— 14.0%	$ 73,517— 14.4%	$ 88,314— 14.9%
ANNUAL RATE OF TURNOVER OF INVENTORY	4.8 times	4.8 times	4.6 times
FLOOR AREA*	2,573 sq. ft.	2,314 sq. ft.	2,672 sq. ft.
SALES PER SQUARE FOOT*	$215.83	$223.45	$219.98
RENT PER SQUARE FOOT*	$ 4.73	$ 4.64	$ 5.30
NUMBER OF PRESCRIPTIONS DISPENSED			
New	14,243— 48.5%	13,796— 47.8%	14,086— 49.7%
Renewed	15,139— 51.5%	15,051— 52.2%	14,261— 50.3%
Total Prescriptions	29,382—100.0%	28,847—100.0%	28,347—100.0%
PRESCRIPTION CHARGE	$12.47	$11.69	$13.04
NUMBER OF HOURS PER WEEK			
Pharmacy was open	61 hours	61 hours	62 hours
Worked by proprietor	50 hours	47 hours	49 hours
Worked by employed pharmacist(s)	37 hours	34 hours	36 hours

* Based on averages of pharmacies that reported all data.
** Source: 1986 *Lilly Digest.*

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*Patent Pending

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LETTERS

Dear Dave:

Just a note to let you know that the VA Baltimore Medical Center Pharmacy and the University of Maryland School of Pharmacy Center for the Study of Pharmacy and Therapeutics for the Elderly will sponsor our 4th Annual Seminar on Thursday, April 30, 1987 again at the Baltimore Hilton Inn on Reisterstown Road. This year's topic wil be, "Chronic Care and the Elderly: An Update", and will feature speakers on vitamins, lipids, cardiovascular, and antibiotic drugs as well as geropsychiatric drugs and nursing care.

Dave, Pete and I greatly appreciate your continued support of our programs.

Sincerely yours,
JOHN T. JORDAN, R.Ph., M.S.
Chairman, Planning Committee

Dear Sirs:

The American Red Cross has the responsibility to provide emergency care during a major disaster. We here in Anne Arundel Co. have identified 7 area schools which we would like to provide with a Disaster Trunk filled with items required for basic care during an emergency. We would greatly appreciate a donation of any of the items listed.

Donations can be directed to 12 S. Crain Hwy. Glen Burnie Md. 21061 or by calling us at 301-760-9600.

We thank you for your generosity.

Contents of Disaster Trunk

MEDICAL:

1 Ice Bag
1 Hot water bottle
3 thermometers—stubby
1 medicine glass
1 eye dropper
1 eye cup
1 scissors
1 pr. tweezers
1 emesis basin
1 bed pan
1 green soap
1 stethoscope
1 sphygmomanometer
2 sewing needles
1 magnifying glass
1 box swabs
12 tongue blades
3 insulin syringes
bandages: 2 × 2 gauze pads
4 × 4 gauze pads
1 box of each
2 triangular bandages
1 box band aids
2 adhesive tape—1″ wide
1 ace bandage
1 box cotton
3 gauze rolled bandgages 2″ and 4″
Alcohol wipes

MEDICINES:

100 acetaminophen adult
2 bottles liquid acetaminophen (pediatric)
1 box bicarbonate of soda
1 bottle spirits of peppermint
10 ammonia inhalants
1 tube benzene hexachloride 1% ointment
4 oz. Betadine Sol.
100 Aspirin Gr. V
1 box antiseptic wipes
1 pt. alcohol
1 small box table salt
1 box cornstarch
1 bottle Ipecac
1 jar petroletum
1 tube burn ointment
3 pk. universal antidote

RED CROSS FORMS:

25 Disaster Nursing Memorandums—#1475
25 Patient Records—2077
4 Activity Sheets
1 Disaster Health Services—3050
(Regulations & Procedures) (Rev. Sept. '82)

MISCELLANEOUS:

2 doz. disposable diapers
1 box facial tissues
1 roll paper towels
1 doz. sanitary napkins and tampons
1 roll toilet paper
4 baby bottles, 8 nipples
12 paper cups
1 bar soap
newspapers
transistor radio
playing cards
paper
crayons
1 roll scotch tape
1 wash basin
1 pitcher
50 ft. clothesline
1 flashlight
1 box thumb tacks
12 straws
12 safety pins
4 batteries
6 plastic trash bags
6 pencils
3 ball point pens
1 steno note book

LINENS:

1 pillow
3 face towels
3 bath towels
3 pillow cases
3 sheets
3 washcloths

TEXTBOOK:

Advanced First Aid & Emergency Care
Second Edition

EXTRAS:

To be gotten from shelter manager when shelter is open.

blankets
chairs
cots
table
waste can
hot plate
2 Standard First Aid Kits (from Chapter)

New Medical Society Executive Named

Angelo J. Troisi, formerly Executive Director of the Prince George's County Medical Society, has been appointed Executive Director of the Medical and Chirurgical Faculty of Maryland. Mr. Troisi will be the chief administrator of the affairs of the Faculty, a non-profit statewide association of 6,000 physicians and medical students dedicated to the delivery of quality health care and the enactment of just laws relating to the practice of medicine in Maryland.

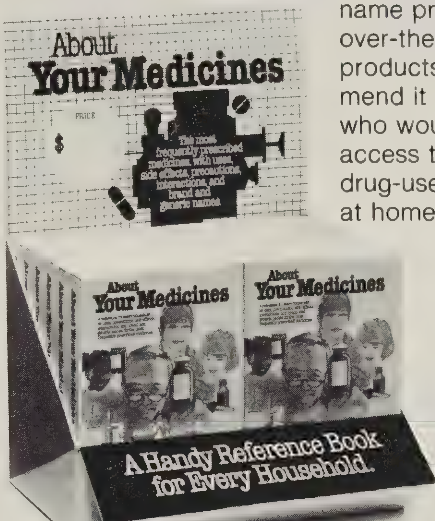
Mr. Troisi has a strong and varied background in numerous facets of health care administration including, Executive Director of the Prince George's County Medical Society, Executive Director of the Maryland Society of Eye Physicians and Surgeons, chief executive officer of various size hospitals and Assistant Professor in the post graduate program of health care administration at Baylor University in Texas. Since 1981, he has been a preceptor in the graduate program of health care administration at George Washington University. Mr. Troisi also has extensive administrative experience with medical services in the military.

Remarking on his plans as Executive Director of the State Medical Society, Mr. Troisi said, "My goal is to ensure that the medical society represents all Maryland physicians and continues to be the patient advocate and protector of quality health care."

Mr. Troisi has a Bachelor's Degree in General Education from the University of Nebraska and a Master's Degree in Hospital Administration from Baylor University. He is a fellow of the American College of Health Care Executives. Mr. Troisi is former Chairman of the Board and current member of both the Southern Maryland Health Systems Agency and the Metropolitan Washington Council of Health Planning Agencies as well as former Chairman of the Board of the Bowie Health Center.

About Your MEDICINES

An abridged edition of selected monographs from *USP DI, Advice for the Patient®*, this easy-to-read family handbook covers the uses, precautions and side effects for over 2000 brand name prescription and over-the-counter drug products. Recommend it to patients who would like to have access to important drug-use information at home. Twelve copies of the paperback come in an attractive display box. A retail price of $5.95 per copy is suggested.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As a Hospital Pharmacist-
how would you describe your job?

If you've ever wanted to show anyone exactly how hospital pharmacists contribute to patient care, now you can with a new videotape . . . the **Invisible Ingredient.**

This production was funded through a grant from Lederle Laboratories.

The videotape takes you one step beyond the "dispensing functions" usually associated with pharmacists by describing the advancement of pharmacy practice and the importance of the pharmacist's contributions in patient care.

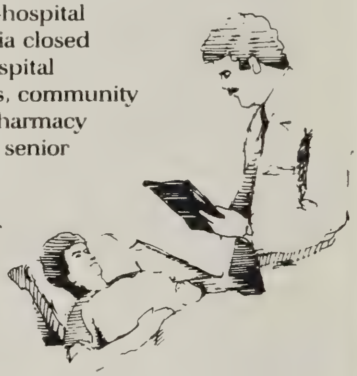
A pharmacy resident shows you around the hospital, explaining how central and satellite pharmacies are set up, and asking the pharmacists in each area specific questions about their particular contributions to the many different pharmacy services. The pharmacists in these areas—pediatrics, ambulatory care, neonatology, oncology, emergency room, intensive care pharmacokinetics—discuss their responsibilities as members of the patient-care team.

You'll also see pharmacists in the drug information center; counseling patients on drug therapy; making rounds; visiting patients at home; and attending a P&T Committee Meeting. The tape emphasizes the specialization and versatility of the pharmacist—in the hospital and in the growing field of home health care. The role of the pharmacist, as an important member of the health care team, is also presented. To this end, the tape shows how physicians, nurses and other health care experts depend upon pharmacists for drug information.

ASHP developed the *Invisible Ingredient* to increase public awareness of the functions of pharmacists in hospitals, home care and other health care environments.

The videotape has many applications—it can be used to inform patients of how the pharmacist becomes involved in their health-care process, as well as to educate pharmacy students on careers in hospital pharmacy practice.

Other audiences for the videotape include—hospital patients via closed circuit hospital televisions, community groups, pharmacy residents, senior citizens groups, consumer groups, hospital public relations offices, health-fairs, college career days, schools of pharmacy . . . plus many others.



The videotape is available in 3/4" or VHS formats.

Order Form

Please send __________ copies of the *Invisible Ingredient* Videotape Check one:

☐ P205A (¾" format) @ $110.00

☐ P205C (VHS format) @ $100.00

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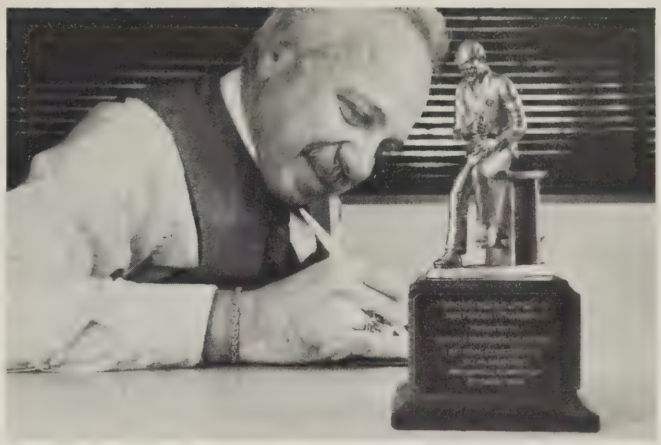
Tom LaMartina received a commemorative mortar and pestle at the end of a ten-week summer internship program with the Upjohn Company. Tom is a graduating Pharmacy Student from the University School of Pharmacy and serves as the Student APhA Chapter's representative to the MPhA Board of Trustees.



Joel Hoffman, Searle's manager of Pharmacy relations, accepted the National Association of Retail Druggists' Corporate Educational Foundation Award at the NARD Convention. Searle was honored for its support of student programs and independent pharmacy activities.

Max Richberg, addressed the Baltimore Metropolitan Pharmaceutical Association's annual meeting held October 7th. Max is chief executive officer for the National Association of Retail Druggists' "RxNetwork," a nationwide Preferred Provider Organization for pharmacists.

At that meeting, Charles Spigelmire delivered his last report as Treasurer for the Baltimore Metropolitan Pharmaceutical Association. He had served in that position for 32 years.

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The Compounders Corner

by
Loyd V. Allen, Jr., Ph.D., and M. Lou Stiles, M.S.
The University of Oklahoma College of Pharmacy
Oklahoma City, Oklahoma 73190

DIAPER RASH PASTE:

Rx	Castor Oil		0.400 g.
	Balsam of Peru		0.200 g.
	Boric Acid Ointment		4.000 g.
	Zinc Oxide Ointment	q.s.	30.000 g.

PREPARATION:

Mix the Balsam of Peru with the Castor Oil. Mix the Boric Acid Ointment thoroughly with the Zinc Oxide Ointment. Combine, via geometric dilution, the Balsam:Castor Oil mixture with the ointment mixture. The finished product should have a uniform brownish appearance.

USE:

Treatment of diaper rash.

PACKAGING:

Air-tight wide mouth plastic or glass jar.

LABELING:

Keep tightly closed; for external use only.

STABILITY:

This preparation is stable, providing the Balsam is completely mixed with the Castor Oil before mixing with the oleaginous bases. It should be kept tightly closed when not in use.

DISCUSSION:

This formulation is oftentimes prescribed for the treatment of diaper rash, or contact dermatitis in infants. The urea in the urine is broken down by bacteria into an ammonia by-product which serves as an irritant to an infant's tender skin, especially those areas around the genitals and the folds of skin, or intertriginous areas.

Petroleum, an oleaginous base, is the primary vehicle for both the Zinc Oxide and Boric Acid Ointments. It serves as an occulsive dressing and provides a protective action to the affected area. Zinc Oxide Ointment contains approximately 20% Zinc Oxide in Petrolatum. The Zinc Oxide component has a mild astringent and antiseptic action; Boric Acid is a weak germicide.

Peruvian Balsam is a dark brown liquid containing between 60 to 64% cinnamein, a volatile oil, and 20 to 28% resin. It is nearly insoluble in water, but soluble in alcohol. The resinous portion of the Balsam presents a compounding problem when incorporating it into an ointment base because it tends to separate upon standing. Castor Oil is utilized in this formulation as a pharmaceutical necessity to facilitate the incorporation of the Balsam.

By introducing the Balsam to an equal or greater portion of Castor Oil and intimately combining the two before incorporation of other ingredients, the risk of separation of the Balsam is greatly, if not completely, reduced.

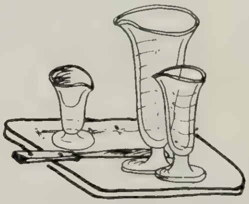
Commercially available Boric Acid Ointment and Zinc Oxide Ointment may be used or they may be "made from scratch". White Ointment is contained in both of these products. White Ointment is a 5% White Wax in White Petrolatum formulation. White Wax, a stiffener, is bleached or purified beeswax.

SOURCE OF INGREDIENTS:

All ingredients employed in this formulation are readily available through local drug wholesalers.

JOIN IN!!!

Send us copies of prescriptions you are compounding. We will list the source of the prescriptions we receive and use in this series.



The authors make no claims concerning the therapeutic efficacy of the products or preparations discussed in this series. These articles are intended to be a forum for extemporaneously prepared nonsterile and sterile prescriptions currently being compounded throughout the United States.

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Classified ads are a complimentary service for members.

Free employment placement service available from the MPhA—Call Beverly at (301) 727-0746.

Hotline for Pharmacists Rehabilitation Committee
(301) 727-0746

FDA Hotline for AIDS 800-342-AIDS

Hotline for impaired Physicians (301) 727-0120

Hotline for impaired Dentists (301) 964-2275

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

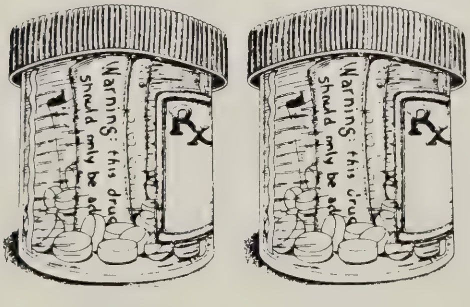
Baltimore City College Alumni

The Baltimore City College Alumni Association is alive and well and vigorously supporting the old Castle on the Hill. The support of all alumni is needed. For an application, please phone 484-5262 evenings.

$10–$360 WEEKLY/Up, Mailing Circulars! No Boses/quotas. Sincerely Interested send self-addressed Envelope: SLH, P.O. Drawer 575, Thorsby, Alabama 35171-0575

Part time pharmacist needed for Saturday hours in Montgomery County call 881-3828 for more information.

For Sale: All steel prescription files. Some in set of six, some individuals. All in excellent condition. Best offer. Call Patty Ensor or David Chason at Sinai Hospital Pharmacy 578-5043.


Warning: this drug should only be ad
Rx
Warning: this drug should only be ad
Rx

calendar

Jan. 14–25—MPhA Trip to Hawaii
Jan. 16–18—MPhA/Alumni Ski Weekend at Hunter Mountain
Feb. 16–24—Alumni/School annual giving Phonathon
March 8—BMPA Annual Dinner Dance
March 15–21—National Poison Prevention Week
April 28–May 1—APhA annual meeting
May 17—CEC Seminar on Arthritis
May 21—Alumni Association annual Graduation Banquet
June 21–25—MPhA convention—Ocean City

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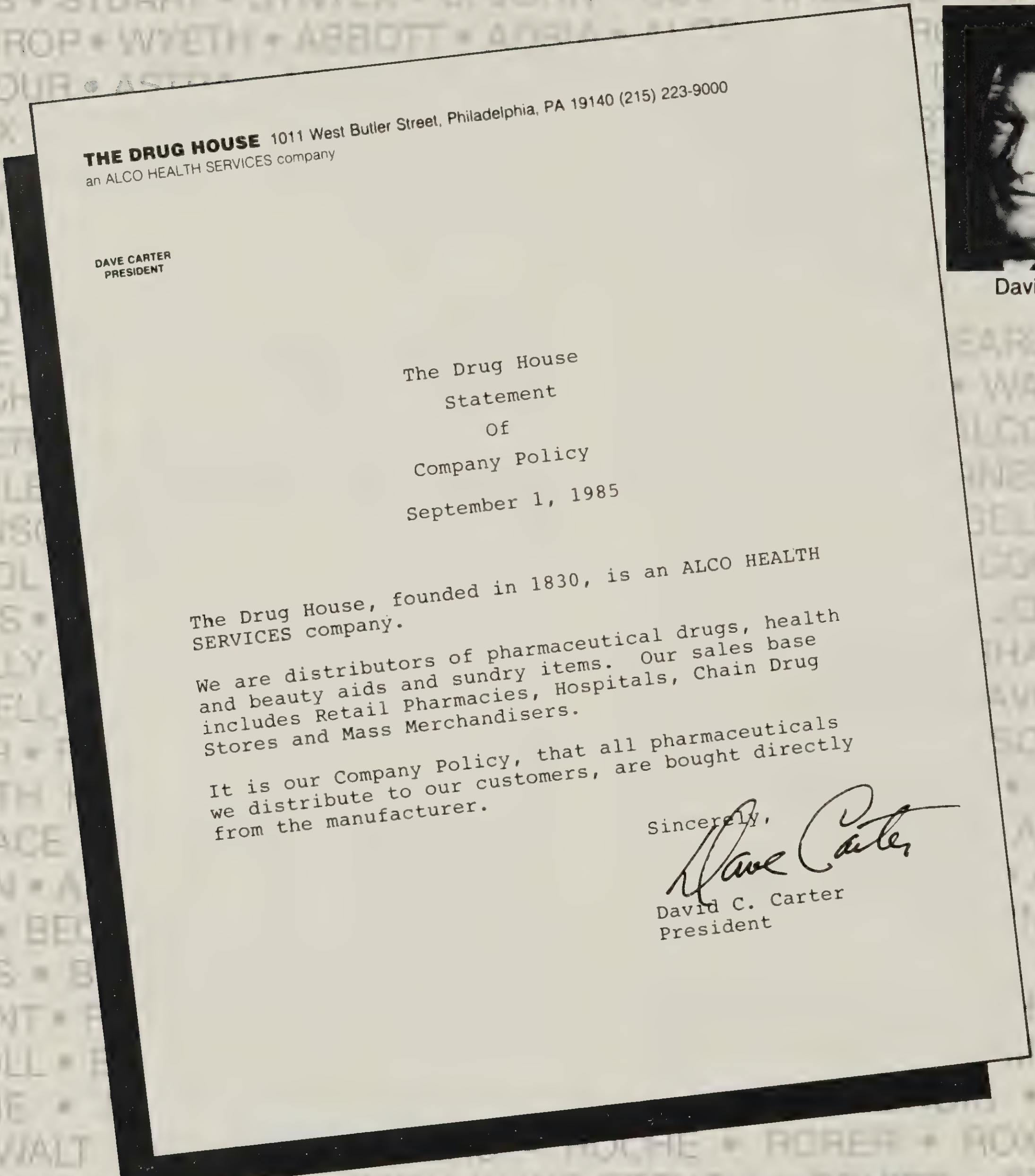

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PRESIDENT

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Of
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Sincerely,

Dave Carter

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President

David C. Carter,
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